"COMPARING THE EFFICIENCY OF FERROUS SULFATE AND FERROUS ASCORBATE IN TREATMENT OF IRON DEFICIENCY ANEMIA IN CHILDREN AGED BETWEEN 1-18 YEARS OF AGE GROUP – A RANDOMIZED CONTROL TRIAL"

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For **(Dr. Harsha Hegde)**
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ABSTRACT

"COMPARING THE EFFICIENCY OF FERROUS SULFATE AND FERROUS ASCORBATE IN TREATMENT OF IRON DEFICIENCY ANEMIA IN CHILDREN AGED BETWEEN 1-18YEARS OF AGE GROUP–A RANDOMIZED CONTROL TRIAL".

INTRODUCTION:

It is estimated that 42% of children aged < 5 years, 45-55% in children less than 12 years are anemic worldwide; the burden is even higher in India with 53.4% of children were found to be anemic in 2021, as per the NFHS-5. Over 30% of anemia is due to Iron deficiency. For the treatment of mild to moderate IDA, oral iron supplementation is employed. Conventionally, ferrous salts are advised, and several bivalent iron salts have been utilized as supplements. Ferrous sulfate, Ferrous Ascorbate are widely in use among them. Iron supplementation with oral formulations should be safe and well-tolerated. For good therapy compliance, iron preparation with favourable tolerability is therefore necessary. The objective of this study is effectiveness of both the salts in terms of their efficacy, tolerability and adverse events during the treatment .

OBJECTIVES:

Primary objective: To study the efficiency of oral iron preparations ferrous ascorbate, and ferrous sulfate in the treatment of iron deficiency anemia in children aged between 1-18 years of age group.

Secondary objective: To study the effects of the salts.

To study the effects of oral preparations.

METHODS: This is a Randomized control trial study conducted at KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, for a period of 1 year from April 2023 to March 2024.

RESULTS: Amongst the 98 children assessed, the mean age of the Ferrous Ascorbate group was 7.21 ±4.62 years and the ferrous sulfate group was 7.31 ±3.67 years. no statistically significant difference was observed between the groups. No Statistically significant difference in the rise in Hemoglobin levels among both groups ($p < 0.001$) .No Statistically significant difference in the rise in ferritin levels among both groups ($p < 0.001$). No Statistically significant difference in the rise in serum iron levels among both groups ($p < 0.001$) . The most common adverse effect observed in the ferrous sulfate group was black tarry stools in 7 (13.4%), metallic taste in 6 (11.5%), diarrhea, constipation, and staining of teeth in 5 (9.6%) children. Adverse effects in the ferrous ascorbate group were constipation in 3 (6.5%), Black tarry stool in 3 (6.5%), fever in 3 (6.5%), diarrhea in 2 (4.3%) and nausea and vomiting in 1 (2.1%) child. Overall Therapeutic effect of both salts is similar and statistically nonsignificant difference. Overall Adverse effects were less observed in the ferrous ascorbate group compared to ferrous sulphate

CONCLUSION:

This study showed that both iron salts are equally efficacious in terms of treating Iron Deficiency Anemia in children aged between 1-18 years; however, due to its better compliance and lesser adverse effects Ferrous Ascorbate has better tolerance than Ferrous Sulfate.

Due to fewer adverse effects compliance and adherence to treatment can be greatly improved with ferrous ascorbate

LIST OF ABBREVIATIONS USED

IDA	Iron Deficiency Anemia
WHO	World Health Organization
NFHS	National Family Health Survey
HCL	Hydrochloric acid
DALY	Disability Adjusted Life Years
MoHFW	Ministry of Health and Family Welfare
PQ	Performance Qualification
ACT	Advanced Coating Technology
EDTA	Ethylene Diamine Tetra Acetic acid
IPC	Iron Polymaltose Complex
AE	Adverse Events
SE	Side Effects
FeS	Ferrous Sulfate
FA	Ferrous Ascorbate
Hb	Hemoglobin
RC	Reticulocyte Count
RBC	Red Blood Cell
HCT	Hematocrit
TIBC	Total Iron Binding Capacity

MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
LBW	Low Birth Weight
RCT	Randomized Controlled Trial
ANOVA	Analysis of Variance
SD	Standard Deviation

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

INTRODUCTION:

Anemia is typically defined as a hemoglobin concentration of 2 standard deviations or more below the mean for a normal population of the same gender and age [1]. Iron deficiency anemia (IDA) occurs in infants and young children mainly due to inadequate dietary iron [2].

Iron deficiency and iron: deficiency anemia (IDA) affect approximately around two billion population worldwide, and most of them reside in low- to middle-income countries. The World Health Organization (WHO) reported that an estimated 42% of children aged < 5 years are anemic worldwide; the burden is even higher in Africa, reaching 62.3%. In Southeast Asia, the prevalence of anemia ranges from 45-55% in children less than 12 years. Anemia is widespread in India 53.4% of children were found to be anemic in 2021, as per the NFHS-5. Maintaining a normal iron balance in these settings is challenging, as iron-rich foods with good bioavailability are of animal origin and expensive and not affordable for most of the population.

There is an association between impaired neurocognitive function in infancy with iron deficiency anemia. Irreversible long-term cognitive defects are also possibly associated with it. Hemoglobin is protoporphyrin, each molecule having 4 iron-containing heme residues.

The kind and amount of iron in food, the presence of dietary promoters and inhibitors of iron absorption, and an individual's iron status all affect the bioavailability and iron absorption from a regular diet. Numerous biomarkers have been employed to evaluate an individual's iron status. These consist of transferrin saturation, total iron-binding capacity, zinc protoporphyrin, serum ferritin, and

hemoglobin. Iron is necessary for most living things, but it may also be poisonous, therefore maintaining systemic iron homeostasis is crucial. The hormone hepcidin, which controls the amounts of the iron-exporter ferroportin in the cell membrane, is responsible for maintaining this equilibrium. Hepcidin binds to ferroportin, causing it to degrade and resulting in less iron being available.

For the treatment of iron deficiency, several types of oral iron supplements are available. Anemia can be prevented and treated with both oral and parenteral iron preparations; however, oral iron preparations are recommended for the treatment of mild to severe iron deficient anemia. Oral preparations are in the form of Ferrous or Ferric salts. The iron preparation that is most commonly used worldwide is ferrous sulfate. Ferrous ascorbate is one of the more recent oral iron preparations; other oral iron preparations include ferrous fumarate and succinate.

A daily dose of 3–6 mg/kg of elemental iron in single or three divided doses is well tolerated by the pediatric age group [3 4]The drawbacks of oral iron therapy include the lengthy course of treatment and problems with adherence. Ferrous salts have been used for this purpose for generations. Aside from the taste of iron, oral iron intolerance in young children is rare. On the other hand, gastrointestinal issues such as heartburn, constipation, tooth discoloration, and black feces can occasionally affect older kids and teenagers [3]. Furthermore, several food components, including phytates, polyphenols, calcium, and tannins, which oxidize ferrous iron to ferric iron [13], decrease absorption from these preparations. Due to the limitations of traditional iron salts, innovative oral iron preparations such as sodium feredetate, carbonyl iron, iron poly maltose complex, ferrous ascorbate, and ferrous bis-glycinate have emerged.

Compared to the ferric form, the ferrous form of iron has therapeutic advantages. None of the dietary inhibitors cause this molecule to dissociate. Iron gets absorbed more easily in vivo from Ferrous ascorbate than from Ferrous Sulphate.

Orally administered ferrous salts are the treatment of choice for iron deficiency. About three times as much iron is absorbed from ferrous salts than from ferric salts. Variations in the particular ferrous salt have relatively little effect on bioavailability; the sulfate, fumarate, succinate, gluconate, aspartate, and polysaccharide-ferri hydrite complex are absorbed to approximately the same extent. The iron content determines the appropriate dosage for each of these medicines. Other iron compounds have utility in fortification of foods. Reduced iron (metallic iron, elemental iron) is as effective as ferrous sulfate provided that the material employed has a small particle size.

Ferrous ascorbate, L- (+)-Ascorbic acid iron (II) salt is prepared from ferrous sulfate which is used as the starting material for the preparation of ferrous ascorbate. Ferrous ascorbate has the advantage of being heat-stable, highly soluble in water, and when combined with ascorbic acid, it enhances bioavailability and lessens side effects. The condition of iron that is most easily absorbed is ferrous. Iron is dissolved by gastric secretion (HCl), which also enables it to combine with ascorbic acid to create soluble complexes. Ferric ions of this kind are reduced to ferrous form with the aid of vitamin C and other chemicals. Plasma iron is transported by ascorbic acid to tissue storage locations. There is also evidence that ascorbic acid improves iron utilization, by its reducing action and it may have a direct effect on erythropoiesis [7].

The effect of iron therapy on individuals was influenced by several factors like stability, solubility and bioavailability of a given drug, the presence or absence of promoters /inhibitors of iron absorption.

The present study is therefore undertaking to compare the efficiency of oral iron preparations, like ferrous ascorbate and ferrous sulfate in children aged between 1-18 years of age group.

AIM & OBJECTIVES:

Primary objectives:

- To study the efficiency of oral iron preparations ferrous ascorbate, and ferrous sulfate in the treatment of iron deficiency anemia in children aged between 1-18 years of age group.

Secondary objectives:

- To study the effects of the salts.
- To study the effects of oral preparations.

REVIEW OF LITERATURE

History of iron deficiency:

Iron deficiency, described in various texts since ancient times, is 'probably the most frequent nutritional deficiency in the world'. Globally about 1.62 billion individuals are said to be suffering from iron deficiency anemia. [1] Around 1500 B.C, *Papyrus Ebers*, which is considered to be the oldest manual of therapeutics, has described a similar disease condition characterized by pallor, dyspnea, and oedema. [2]

In 1713, Lemery and Geoffroy, and in 1747, Menghini found residual particles which were attracted to lodestone after burning blood to ash and thus presumed those particles to be made up of iron. The German biochemist Felix Hoppe-Seyler (1825–1895), using absorption spectrometry showed that hemoglobin is made up of a complex of hematin and protein. Stokes (1819–1903), a professor of mathematics at the University of Cambridge, showed that hemoglobin exists in two forms and demonstrated the changes between them in response to oxygen administration.

Bunge (1902, Basle) was the first to suggest the fact that iron deficiency caused hypochromic anemia. He also showed that iron was found in higher concentrations in the liver and kidneys of newborn infants than in older infants, children or adults. He also stated that iron content in human milk was very low and the iron derived from hemoglobin in meat was poorly absorbed. This fact was very much in contrast to today's evidence which suggests that haem iron is rapidly absorbed from the gastrointestinal tract. He was the first to recognize that a high concentration of iron was present in egg yolk, spinach, apples, lentils and beef.

Koilonychia, a particular form of iron deficiency that is often referred to as "Lydney hand" in ancient literature, was first documented in the 20th century by Kaznelson (1931).

In the middle of the 16th century, European physicians treated a disease condition known as chlorosis or "green sickness". This condition had been treated with iron salts and other remedies (including, oddly enough, phlebotomy) in France, by the middle of the 17th century. Not long thereafter, Sydenham had also recommended iron as a specific remedy for chlorosis. [3]

In 1832, pills containing 1.39 g of ferrous sulphate and 0.1 g of potassium carbonate were widely recommended for chlorosis and other conditions. These pills were introduced by Blaud. The original pill was made with 64 mg of iron. Later on, arsenic was often included in these pills as many physicians thought iron combined with arsenic was more effective. This same trend continued even into the 1930s

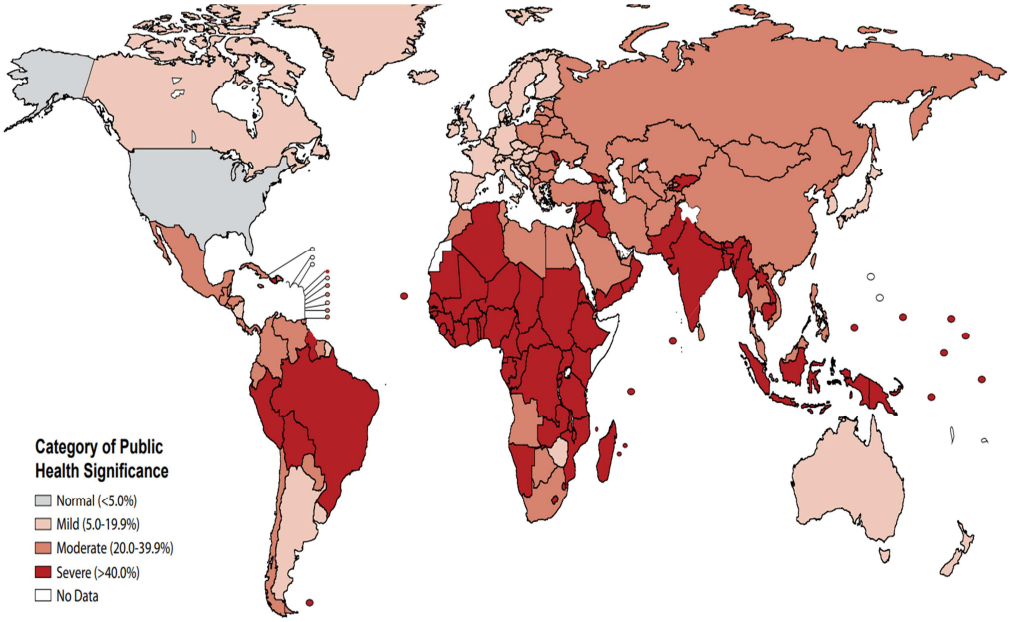
Finally, the study of blood cell morphology was made possible by the pioneering work of Paul Ehrlich (1854–1915) who developed aniline dyes to stain blood films and led to the birth of modern hematology.

Only after the 1932 studies by Heath, Strauss, and Castle that it was shown that the response of anemia to iron was stoichiometrically related to the amount of iron given and that chlorosis was, indeed, iron deficiency.

Prevalence:

Iron deficiency is the most widespread nutritional disorder in the world. Anemia is the most common problem among micronutrients deficiency. Anemia affects health, education, economy and thereby, the productivity of the entire nation.

Thus, anemia constitutes a public health epidemic. The numbers are staggering. Over 30% of the world's population is anemic, mainly due to iron deficiency. This figure is frequently exacerbated by malaria and worm infections in developing countries.



Source: WHO Global Database on Anaemia

Figure 1. WHO Demographics of Anemia

Impact of anemia in South East Asia:

South East Asia has the largest number of anemic persons, including children contributing to 12,500,000 Disability Adjusted Life- Years (DALYs) and 324,000 deaths in this region, which is the highest in the world. More than 66% of the children in this region are anemic. In children aged less than two years, the prevalence of anemia may exceed 90%. [4]

Anemia has been a big public health problem in India. The prevalence of anemia among children less than five years of age has been shown to be around 67%

as per the data collected by National Family Health Survey (NFHS) V. [5]

Iron deficiency affects the activity of numerous enzymes adversely. Infants, whose organs are still developing, including the brain, are affected significantly by anemia resulting in growth retardation and impairment of intellectual development.

Table 1: Prevalence of Iron Deficiency Anemia

	NFHS	**Children aged 6-59 months who are anemic (<11.0 g/dl) (%)**	**Adolescent girls aged 15-19 years who are anemic (%)**	**Adolescent boys age 15-19 years who are anemic (<13.0 g/dl) (%)**
India	**NFHS-5**	67.1	59.1	31.1
	NFHS-4	58.6	54.1	29.2
Karnataka	**NFHS-5**	65.5	49.4	26.5
	NFHS-4	60.9	45.3	24.5

At the same time, iron deficiency anemia can usually be prevented easily at a very low cost. In the field of public health, the cost-benefit ratio of instituting preventative interventions for iron deficiency is acknowledged as one of the highest.

Source: HFW/PQ/ ANAEMIA MUKT BHARAT/4th February 2022/

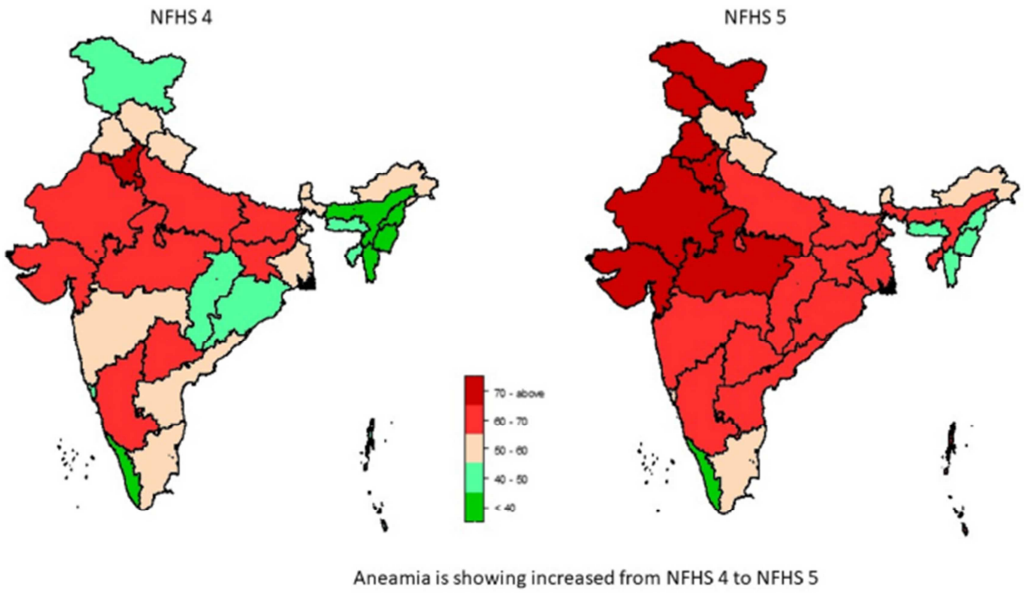


Figure 2. Demographics of Anemia in India showing trends among NFHS IV and NFHS V

Source: Predicting child anemia in the North-Eastern states of India: a machine learning approach by Jiran Meitei's Compilations Based on NFHS-4 and NFHS-5, Published by MoHFW, Govt. of India

Pathophysiology of anemia in children:

At birth, hemoglobin concentrations are normally higher than at any other time of life. This occurs as a result of the adaptation of the foetus to the hypoxic environment of the uterus. Additionally, the newborns have comparatively large stores of stored iron

From two months of age, the hemoglobin concentration starts declining from a mean of 17.0 g/dL at birth and reaches a low level of 11.0 g/dL. This occurs due to breakdown of hemoglobin in order to meet the iron needs. This decrease in hemoglobin concentration is known as 'early anemia of infancy'. This condition is

usually unresponsive to iron treatment and hence, distinguished from the 'late anemia of infancy'. Therefore, between birth and four months of life, a term infant's total body iron levels essentially remain unchanged, and throughout this time, there is only a minimal requirement for exogenous iron.

After about four months of age, the period of continued rapid growth begins and a gradual shift to marginal iron reserves occurs. Between four and twelve months, blood volume is rapidly expanding and a large amount of iron is needed in order to maintain a near-constant mean hemoglobin concentration of 12.5 g/dL. During this time, the children are particularly susceptible to iron deficiency.

By four to six months of age, dietary iron absorption becomes important as iron stores are usually depleted. Low birth weight babies have less iron stores and hence, they need extra iron as well as iron at an early age from the diet source.

During the first 15 years of life, an average of 0.8 mg of iron needs to be absorbed each day. In addition, a small amount is also needed to balance normal losses of iron caused by shedding of cells. Therefore, approximately 1 mg of iron is needed daily in order to maintain a positive iron balance in childhood. This can be achieved by ensuring a dietary intake of 8-10 mg of iron daily since only 10% of dietary iron usually is absorbed.

When growth is most rapid, approximately 1 mg/L of iron in bovine and breast milk makes it difficult to maintain the body iron. Breastfed infants have an advantage because they absorb iron 2-3 times more efficiently than infants fed with bovine milk.

Hemoglobin levels:

Table 2: World Health Organization defined criteria, using hemoglobin levels for anemia classification[7]

Age groups	No Anaemia	Mild	Moderate	Severe
Children 6–59 months of age	≥11	10–10.9	7–9.9	<7
Children 5–11 years of age	≥11.5	11–11.4	8–10.9	<8
Children 12–14 years of age	≥12	11–11.9	8–10.9	<8
Non-pregnant women (15 years of age and above)	≥12	11–11.9	8–10.9	<8
Pregnant women	≥11	10–10.9	7–9.9	<7
Men	≥13	11–12.9	8–10.9	<8

Source: Haemoglobin concentration for the diagnosis of anaemia and assessment of severity. WHO

Iron deficiency anemia:

Iron deficiency is defined as a condition characterized by signs of compromise in the supply of iron to tissues including the erythrocyte, as there are no mobilizable iron stores. The most common causes of iron insufficiency are increased iron requirements during rapid growth, insufficient bioavailable dietary iron, and excessive blood loss for any cause. [6]

Anemia, when caused by severe iron deficiency is termed as iron deficiency anemia (IDA) and represents a very late stage of iron deficiency. Iron deficiency anemia is commonly associated with decreased physical capacity, reduced immunity and cognitive impairment. Severe iron deficiency anemia also affects the capacity to maintain body temperature and is also life-threatening. [7]

Table 3: Causes of iron deficiency anemia:

Decreased intake or absorption	• Insufficient dietary iron • Too early introduction or delayed introduction of complementary feeding without supplementation of iron • Poor bioavailability due to increased absorption inhibitors and decreased absorption enhancers
Increased requirement	• Rapid growth phase in infancy and early childhood
Increased blood loss	• Infections (hookworm, Trichuris trichura, plasmodium, helicobacter pylori) • Gastrointestinal blood loss (Meckel's diverticulum, peptic ulcer, oesophagal varices, hemorrhoids, hereditary telangiectasia, ulcerative colitis, diverticulosis, angiodysplasia) • Other causes (Hemoglobinuria, Widespread bleeding disorders) • Malabsorption (Gluten-induced enteropathy, gastrectomy, atrophic gastritis, chronic inflammation) • Bovine milk allergy

Iron Supplementation

For the treatment of mild to moderate IDA, oral iron supplementation is employed; parenteral therapy is required for severe cases. For patients who are malabsorbent or have an intolerance to oral iron preparations, parenteral preparations are also the recommended option. Iron supplementation with oral formulations should be safe and well-tolerated. In order to reach the desired hemoglobin levels, iron

supplementation needs to be continued for at least two months. For good therapy compliance, iron preparation with favourable tolerability is therefore necessary. Numerous elements, such as the degree of anemia, the existence of other medical conditions, the iron salt, its absorption, bioavailability, and most crucially, tolerance, all affect how the body reacts to iron supplements. [8]

The addition of iron in underdeveloped nations has many obstacles. The majority of Indians follow vegetarian diets, and the food contains high levels of inhibitory ligands such as phytates, phosphates, tannins, and polyphenols, which prevent the body from absorbing iron by oxidizing ferrous iron to the ferric form.

Overview of Iron Absorption

The physiological form of iron that the intestines absorb is when it is in the ferrous state. In the small intestine's alkaline pH, iron in the ferric is transformed into insoluble ferric hydroxide, which has a low absorption capacity.

Ferric species must be converted to ferrous iron, which is subsequently delivered into the enterocytes through the membrane, in order for the intestinal mucosa to absorb trivalent iron [9]. As a result, free radicals are created. Another advantage of ferrous ascorbate is its reducing impact of ascorbate, which protects against cellular damage from free radicals.

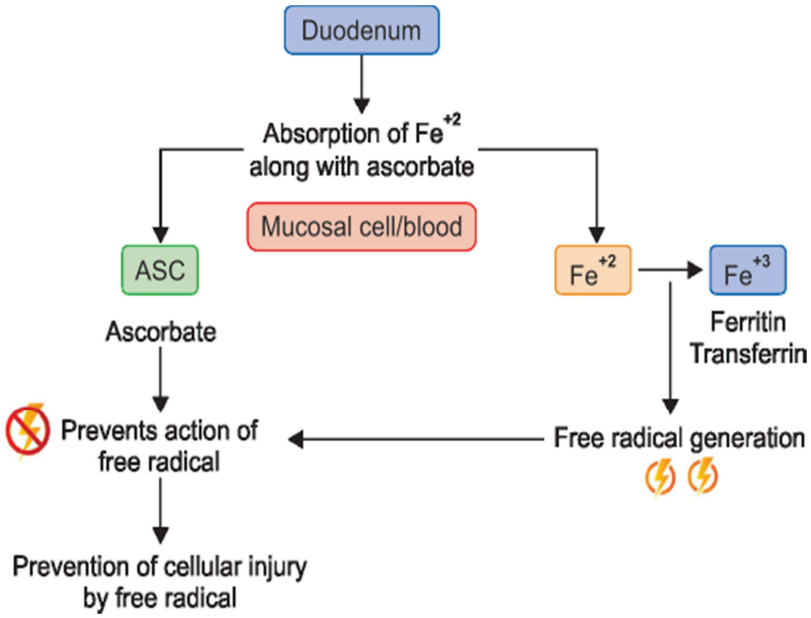


Figure 3 Overview of Iron absorption

Table 4: Dietary iron absorption:

Haem iron absorption	• Iron status • Haem iron in the diet • Fish, meat, poultry. • Constitutes less than 10% of the totalintake in developing countries. • However, bioavailability is high. • Calcium content in meal (e.g. milk,cheese) • Method of food preparation (temperature, time)
Non-haem iron absorption	• Iron status • Dietary non-haem iron • Cereals, pulses, vegetables, tubers • Bioavailability is low • Contamination iron • Soil, dust, water, iron pots

Table 5: Enhancers and inhibitors of iron absorption:

Enhancingfactors	Ascorbic acid present in fruits, fruit juices, vegetables Fish, meat, chicken
Inhibiting factors	• Phytates and other inositol phosphates • rice (unpolished), oats • breakfast cereals, • bread • Calcium (e.g. milk, cheese) • Iron binding phenolic compounds • tea, coffee, cocoa, certain spices, • certain vegetables • most red wines, Nuts, peas, soybeans

Factors Influencing Iron Absorption

The kind of salt used for medicinal iron, the amount given, the dosage schedule, and the volume of iron reserves all affect how well iron is absorbed. After oral therapy, iron from supplements containing ferric forms must be transformed into ferrous forms in order to be absorbed. There are therapeutic benefits to the ferrous form of iron as opposed to the ferric form [11] [12]. The clinical efficacy of iron III hydroxide poly maltose is unknown, and its bioavailability is poor (three to four times lower than that of the ferrous version). For three months, oral ferric protein succinylate tablets (n = 30) and ferrous glycine sulfate tablets (n = 34) were given to twelve IDA women. The ferrous preparation resulted in greater mean hematocrit (2.62 vs 5.91%) and Hb (0.95 vs 2.25 g/dL). [13]

Ferrous Salts for Oral Iron Therapy and Supplementation

Conventionally, ferrous salts are advised, and several bivalent iron salts have been utilized as supplements. Ferrous sulfate, fumarate, gluconate, glutamate, succinate, and lactate are a some of them. Unlike other ferrous salts in iron supplements, ferrous ascorbate is known to stay soluble in the small intestine's alkaline pH. [14] Iron preparations with ascorbate aid in boosting iron uptake and avoiding iron excess. This is explained by the iron being mobilized from the ferritin core to the erythropoiesis sites and by ascorbic acid inhibiting the ferritin to hemosiderin conversion.[14 15]

Ferrous ascorbate has comparable efficacy to ferrous sulfate which is a commonly used iron preparation in clinical practice. Intestinal absorption of iron determined on day 21 in a study involving 18 healthy phlebotomized participants who received either a quick-release ferrous ascorbate preparation or a prolonged-release ferrous sulfate formulation did not differ.[16]

Following two months of treatment, the increase in Hb was comparable in this trial. In individuals with IDA, Panchal et al. found that ferrous ascorbate and iron sulfate were equally effective.10 Worldwide research employs ferrous ascorbate as a reference molecule. [14 17]

FERROUS SULPHATE

Chemistry

An inorganic salt called ferrous sulfate is used to treat patients receiving epoetin as well as those with iron deficiency and iron deficiency-induced anemia. After oral administration, ferrous (Fe+2) sulfate is absorbed more easily than iron in

its ferric (+3) form. Two forms of ferrous sulfate are used: heptahydrate and anhydrous. The heptahydrate form has 20% elemental iron (by weight), while the anhydrous form has 32.5% elemental iron.

Pharmacokinetics

- Onset of action: Hematologic response: Oral: ~3 to 10 days
- Peak effect: Reticulocytosis: 5 to 10 days; hemoglobin increases within 2 to 4 weeks
- Absorption: In the duodenum and upper jejunum; in persons with normal serum iron stores, 10% of an oral dose is absorbed; this will be increased to 20% to 30% in persons with inadequate or insufficient iron stores. Food and achlorhydria can decrease absorption
- Protein binding: To transferrin
- Excretion: via Urine, sweat, sloughing of the intestinal mucosa, and menses

FERROUS ASCORBATE

Chemistry

Ascorbic acid and iron in the ferrous state are synthesized to form ferrous ascorbate. Ferrous ascorbate has a special chemistry that results from the high iron content and iron's coexistence with ascorbate in the same molecule.18 More than 200 mg of ascorbic acid enhances the absorption of medical iron by at least 30%. [17] Ascorbic acid and iron concentrations are both high in ferrous ascorbate (12–15%). [14]

Ferrous ascorbate responds quickly; improvement in hemoglobin levels can be shown as soon as 15 days after starting a ferrous ascorbate dose.[15] Ferrous ascorbate's

apparent high performance, great safety record, and tolerable iron content can be attributed to its chemical state's advantages, which include improved iron bioavailability and usage.

When compared to iron in the ferric form, the chemical state of ferrous iron seen in oral supplements is clearly superior. Ferrous preparations are recommended for oral iron supplementation over ferric preparations due to their superior effectiveness, reasonable tolerance, and inexpensive cost. [13]

Pharmacokinetics

Iron in conventional ferrous salts is subject to oxidation by the alkaline medium in the gastrointestinal tract and by food constituents. Iron is absorbed as much as possible in the ascorbate preparation because:

It inhibits the conversion of ferrous to ferric iron, which improves absorption; inhibition of the production of insoluble iron complexes that obstruct iron absorption as well as the impact of phosphates, phytates, and oxalates on iron absorption. [15 19] certain intrinsic properties of ferrous ascorbate aid in its absorption.

Ferrous ascorbate dissociates to create monomeric cations in aqueous solutions. Between pH levels of 6 and 8, ferrous ascorbate has an ascorbate solubility-enhancing effect. [20] Higher absorption results from stabilizing the ferrous ascorbate chelate and preventing it from dissociating in the presence of stomach inhibitors through a unique manufacturing process that includes advanced coating technology (ACT).

Comparison of Bioavailability of different iron preparations:

The bioavailability of 59Fe III hydroxide poly-maltose was found to differ significantly from that of 59Fe labeled-bivalent iron preparations, such as ferrous ascorbate or a quick-release ferrous sulfate, in a study comparing ferric and ferrous oral iron preparations. Compared to ferrous ascorbate (43.7 ± 7.1%), intestinal iron absorption during fasting was lower for the Fe III complex (1.2 ± 0.1%). Following a meal, there was no change in the absorption of the ferrous preparation, while the absorption of the ferric preparation rose to 8.8 ± 4.7%. The ferrous preparations showed a higher daily rise in Hb concentration (1.1 ± 0.3 g/L) following an equivalent therapeutic dose of 100 mg elemental iron over 28 days, in comparison to the Fe III hydroxide-poly maltose complex (0.68 ± 0.2 g/L) [24 25]. Of the oral iron formulations currently available, only approximately 1–8% of iron is absorbed. The degree of elemental iron absorption from different iron preparations is displayed in Table 2 [23 26-31]

Ferrous ascorbate has a high bioavailability. In a study in 45 healthy males, the National Institute of Nutrition, Hyderabad, reported absorption of 8.3, 6.3, and 0% iron from ferric orthophosphate, sodium iron pyrophosphate, and ferric pyrophosphate, respectively, and 30.6% from ferrous ascorbate 21 Several studies have reported a similarly high absorption (39–43.7%) of iron from ferrous ascorbate and absorption as high as 67% is reported in the state of iron deficiency with anemia. [22 23] The geometric mean absorption from ferrous sulfate, ferrous ammonium phosphate, and ferric pyrophosphate was 10.4, 7.4, and 3.3%, respectively, in a bioavailability study of iron compounds.[24] The presence of ferrous iron as a chelate with ascorbate and the fact that ascorbate prevents or delays the oxidation of ferrous

iron account for the higher absorption of iron from ferrous ascorbate as opposed to ferrous sulfate. When compared to the uptake from other forms of iron, ferrous ascorbate has the highest percentage uptake regardless of the iron status. In order to simulate iron-deficient and iron-overload conditions as well as the presence of divalent metal cations, Yeung et al. examined the iron uptake from radiolabeled ferrous sulfate, ferrous ascorbate, ferrous bis-glycinate, ferric chloride, ferric citrate, and ferric EDTA by Caco-2 cells with varying iron status. Cells getting supplemental iron demonstrated significant reductions in uptake from ferrous bisglycinate and radiolabeled ferrous ascorbate, but not from ferric compounds, when compared to cells receiving no additional iron. Ferrous ascorbate had the highest percent reduction (−90%). [32] Ferrous form of the iron has the greatest absorption efficiency.

Comparison of efficacy of different oral iron preparations:

It has been demonstrated that ferrous ascorbate is more effective in children when compared to other iron salts. In a trial comparing the effects of ferrous ascorbate and iron poly maltose complex (IPC) at a dose of 6 mg/kg for the treatment of IDA in children, both groups' baseline Hb levels were significantly improved at 12 weeks. With ferrous ascorbate and IPC, the increase in Hb was 4.88 + 1.28 g/dL and 3.33 + 1.33 g/dL, respectively, and the improvement in Hb was substantially higher for ferrous ascorbate ($p < 0.001$). [35] There is mixed evidence for the efficacy of IPC in the treatment of IDA.

Studies have shown that it is just as effective as ferrous sulfate or other salts for raising Hb, with some reporting no discernible differences in this regard [36-37] [38] Better efficacy has been reported for ferrous ascorbate compared to colloidal iron preparation. Ferrous ascorbate (n = 41) and colloidal iron (n = 39) were compared in

an open-labeled, randomized, parallel-group study with children (6 months to 12 years old) with IDA (Hb <10 g%). The results showed that at 12 weeks, ferrous ascorbate significantly increased Hb levels compared to colloidal iron (3.24 ± 1.66 g% vs 1.42 ± 2.04 g%; p <0.01).[39] Children in this study were given 3 mg/kg/day of elemental iron for a duration of 12 weeks.

Responder rate (Hb ≥ 11.5 g%) after 12 weeks of therapy was also significantly higher for ferrous ascorbate (53.57 vs 10.34%; p <0.01). At 12 weeks, the mean increase in hemoglobin was greater in the ferrous ascorbate group (3.59 ± 1.67 vs. 2.43 ± 1.73 g/dL; p <0.01) when compared to the colloidal iron group. 40 In an open-label, randomized, comparative study of ferrous ascorbate (n = 30) and carbonyl iron (n = 30) in the treatment of IDA, ferrous ascorbate showed a significantly (p <0.05) greater increase in Hb (5.03 ± 1.81 vs 2.82 ± 1.43 g/dL above baseline).[33]

When treating IDA, iron ascorbate works better than ferrous sulfate. Singhal et al. conducted a prospective, randomized, comparative clinical trial and reported a significant and comparable rise in Hb on days 30 and 60 with ferrous sulfate (100 mg), fumarate (100 mg), ascorbate (100 mg), sodium feredetate (33 mg), and 30 mg of ferrous bisglycinate in the IDA treatment of 250 pregnant women with hemoglobin levels between 7 and 10 g%. (40,41) At day 60, the rise in Hb was significantly more with ferrous ascorbate (1.13 ± 0.35; p = 0.024) and ferrous bisglycinate (1.11 ± 0.27; p = 0.014) as compared to ferrous sulfate. Ferrous ascorbate was most frequently prescribed (69.2%)

In a retrospective review of hospital records of 250 individuals with anemia (15–35 years of age) receiving treatment in a teaching hospital in India., followed by ferrous sulfate (13.6%), ferrous fumarate (9.6%), and ferric ammonium citrate (7.6%).19 In an open-label, prospective research conducted in clinical settings in India, ferrous ascorbate demonstrated good effectiveness (Table 2). [15]

Table 6: Reported absorption of elemental iron from various iron preparations

Iron preparation	**Absorption (%)**
Ferrous ascorbate	67
Ferrous sulfate	7.7–10.9
Iron polymaltose	8.8
Ferric ammonium citrate	2.4
Ferric hydroxide	2.4
Ferric orthophosphate	8.3
Sodium iron pyrophosphate	6.3
Ferric pyrophosphate	0
Ferrous fumarate	3–6.3
Ferrous bisglycinate	6–9.1
Ferrous gluconate	Less than or equal to ferrous sulfate
Carbonyl iron	70% of ferrous sulfate

Ferrous ascorbate (n = 30) and carbonyl iron (n = 30) were compared for iron deficiency anemia (IDA) in an open-labeled, randomized research.[33] Patients were given the two formulations for 60 days at a dose equal to 100 mg of elemental iron. Compared to carbonyl iron (2.82 ± 1.43 g/dL), ferrous ascorbate caused a much higher mean increase in hemoglobin (5.03 ± 1.81 g/dL). 93.33% of patients were made nonanemic with ferrous ascorbate, compared to 46.66% with carbonyl iron [absolute risk reduction: 46.67%; (99% CI = 17–76.2%); relative risk reduction: 88%; number needed to treat: 2.1]. This indicates that the responder rate was greater with ferrous ascorbate. Ferrous ascorbate caused a greater elevation in serum ferritin (53.20 ± 13.35 vs. 38.22 ± 15.21 µg/L; p = 0.0002). Additionally, ferrous ascorbate has been used to prevent anemia in surgical patients.

Prophylactic administration of ferrous ascorbate (99 mg elemental iron) beginning one week prior to the patients' first blood donation and continuing for up to two months following the procedure recovered Hb and ferritin levels in 68 patients undergoing orthopedic surgery and autotransfusion in a prospective study. There are currently 34 newer generation iron preparations on the market, like sucrosomial. It is claimed that these formulations offer improved clinical outcomes, tolerability, compliance, and absorption rates.

It is worth mentioning that these formulations only contain 30 mg of elemental iron and are now permitted for use as dietary supplements in India. As a result, the therapeutic use for managing IDA is limited. Sucrose iron's high bioavailability is not supported by any human study data. There is little clinical evidence for these preparations, and the majority of the trials had tiny sample sizes.

According to one trial, a 120 mg dose increased Hb, however 26% of patients experienced gastrointestinal adverse effects as a result. [42] Evidence that has been published has shown that taking too many or too frequent pills can cause noncompliance with iron deficiency treatment, which may be crucial for the management of iron deficiency anemia. [43] Similarly, taking sucrosomial iron more than thrice a day may have a negative effect on therapy compliance.

Safety of ferrous sulphate:

With oral iron supplementation, safety is a major concern because gastrointestinal unpleasant effects can occur in as many as 50% of patients, which can lower compliance. [42] Age, body mass, and genetic variations affecting tolerance all have an impact on how well oral iron supplementation is tolerated by the patient. [19] Daily ferrous sulfate supplementation was associated with 2.6 times the risk of gastrointestinal side effects in individuals compared to placebo or IV iron. Due to side effects, adherence to ferrous sulfate during pregnancy has only been found to be between 70 and 90 percent.

Two latest Cochrane reviews provide the better comprehensive analysis of oral iron therapy [14,15] and draw on data from 11 trials (n = 4418 participants) reporting side effects. According to Pena-Rosas et al., individuals who took oral iron supplements had a higher likelihood of reporting adverse effects than those who did not (25.3% versus 9.91%: RR 2.36; 95% CI 0.96–5.82), especially when the dose of elemental iron was greater than 60 mg. 14 Compared to those who received daily iron supplements, those who received intermittent oral iron supplementation experienced fewer side effects (mean RR 0.56; 95% CI 0.37–0.84)[15].

Here, we've employed oral ferrous sulfate, and while there is a lot of variation in the data, our results also indicate that ferrous sulfate is linked to a significantly higher occurrence of gastrointestinal side effects (OR = 3.33, p = 0.02).

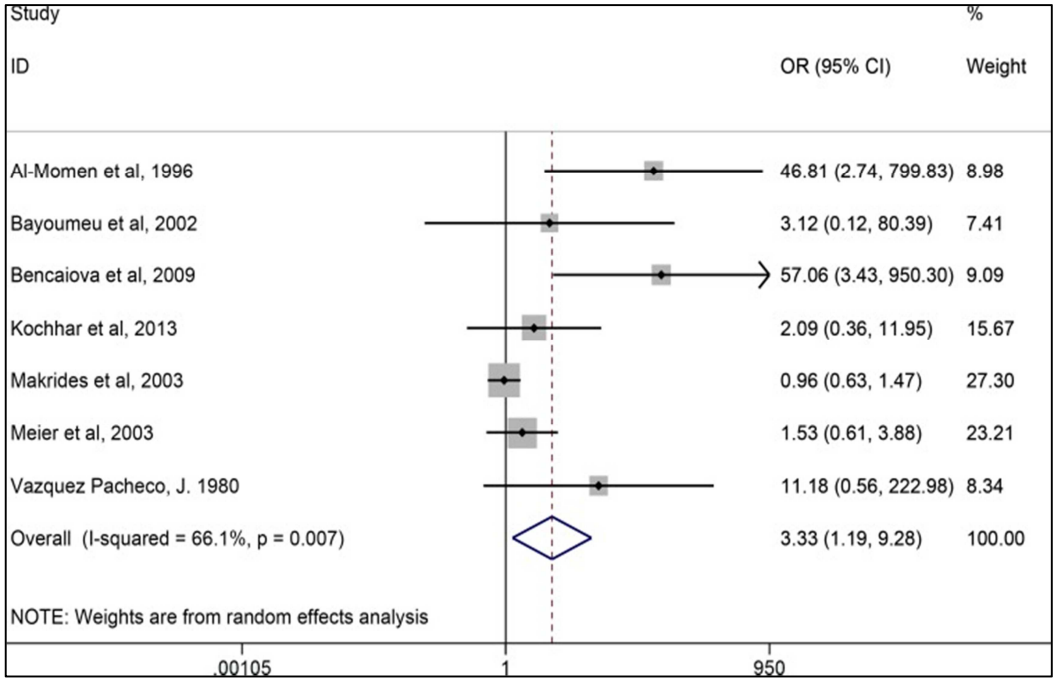


Figure 4. Forest plot demonstration for daily supplementation of ferrous sulfate on the occurrence of gastrointestinal side effects.

Safety of ferrous ascorbate

Ferrous ascorbate is well tolerated and has an excellent safety profile. Ferrous ascorbate minimizes the likelihood of gastrointestinal side effects while supplying the duodenal brush border with the highest potential concentration of ferrous iron. [15]

In a practical application, ferrous ascorbate was favorably tolerated. Gastrointestinal AEs were reported in 7.05% (95% CI: 5.79–8.49%), which included acidity, loose stools, constipation, gastritis, nausea, vomiting, and black stools. [15] When taking iron supplements with food and in daily dosages no more than 180 mg

elemental iron, the likelihood of experiencing gastrointestinal distress is generally low. [18] Ferrous ascorbate is also well-tolerated in children.

Ferrous ascorbate was found to be well-tolerated and to have no documented adverse effects in a 12-week research comparing the effects of ferrous ascorbate and colloidal iron supplementation at levels of 3 mg/kg/day in 80 children ages 6 months to 12 years.

The highest number of adverse events (AEs) were recorded with ferrous fumarate (51 AEs), followed by ferrous sulfate (40 AEs), ferrous bisglycinate (26 AEs), ascorbate (18 AEs), and sodium feredetate (10 AEs), in a comparative assessment of ferrous sulfate (100 mg), fumarate (100 mg), ascorbate (100 mg), and ferrous bisglycinate (30 mg) in antenatal women. 40 Treatment discontinuations were not linked to any of the iron formulations.

Table 7: Comparison of studies based on drug side effects:

Author, year	Participants (N; age)	Dose of iron (mg/kg/d)	Duration of treatment	Interventions (n)	Study findings
Powers, 2016 [9]	59, 9-48 months	3	12 weeks	Ferrous sulphate (28), Iron polysaccharide (31)	E[a]: FeS[c] >IPC (P<0.001) SE[b]: IPC >FeS (P=0.62)
Name JJ, 2016 [13]	20; 1-13 year	3	45 days	Iron bisglycinate Chelate (FeBC), Polymaltose iron	E: IPC[d] = FeBC (P =1)
Yasa, 2009 [10]	103; 7months-17 years	5	4 months	IPC (52), Ferrous sulphate (51)	E: FeS >IPC (<0.001) SE: FeS >IPC (P=0.012)
Patil, 2016-2017 [15]	100; 1-12 years	6	3 months	IPC (50), Ferrous ascorbate (50)	E: FA[e] >IPC(P<0.001)
Pineda, 2001 [12]	40; 6-36 months	5	28 days	Ferrous sulphate (20), Ferrous bisglycinate chelate (20)	E: FeS=FEBC (P=1)
Yewale, 2008 [14]	66; 6 months - 12 years	3	12 weeks	Ferrous ascorbate (37), Colloidal iron (29)	E: FA >C.iron P<0.001)
Bopche, 2004 - 2005 [8]	106; 1-6 years	6	1 month	IPC (53), Ferrous sulphate (53)	E: FeS >IPC (P<0.001) SE: FeS=IPC (P=0.14)
Ozsurekci, 2009 [11]	60; 6 months – 15years	6	8 weeks	ferrous sulphate, Polymaltose complex, Iron-zinc	E: FeS=IPC (P=0.068)

A Efficacy defined by a significant increase in hemoglobin (P< 0.05);
B gastrointestinal side effects.
C FeS: ferrous sulphate; IPC: iron poly maltose complex; FA: ferrous ascorbate; C. Iron: colloidal iron. Hb: hemoglobin; TIBC: total iron binding capacity; MCV: mean corpuscular volume; MCHC: mean corpuscular hemoglobin concentration; MXH: mean corpuscular hemoglobin.

REVIEW OF LITERATURE

- Aggarwal et al., in 2004 conducted a study among predominantly breast-fed term low birth weight (LBW) infants aged 50–80 days to evaluate the hematological effects of iron supplementation. A total of 73 infants enrolled were randomized into two groups. One group received iron (3 mg/kg/day) and the other group received placebo drops. Baseline anthropometry and hematological parameters were measured. These measurements were repeated after four and eight weeks and no significant differences were found in serum ferritin and anthropometry. However, there was a significant positive change in hemoglobin levels in the iron supplementation group. [44]

- In 2004, a review article published in Indian Pediatrics regarding iron supplementation recommended oral iron for treating iron deficiency anemia. According to the article, the type of iron salt to be used has to be based on the bioavailability of the iron salt, side effects and cost-effectiveness. [45]

- Ferrous salts, specifically ferrous sulfate, are preferred for the treatment of Iron Deficiency Anemia since all iron needs to be reduced to ferrous form for absorption. As ferrous sulfate is not stable in liquid form, other ferrous salts are used in liquid formulations. One important side effect of ferrous sulfate is gastrointestinal intolerance. Various measures have been suggested to overcome this side effect. These measures include administration after meals and at bedtime, since decreased intestinal motility during sleep may help improve absorption.

- In the case of ferric salts, ferric ammonium citrate is used. The important drawback of these salts is the low bioavailability which is considered to be 3-4 times less than ferrous salts.

- Better bioavailability is claimed with iron-amino acid chelators, which are other group of iron preparations because absorption of this salt is said to be not interfered by phytates in the diet. However, when compared to ferrous sulfate in clinical studies in young children and infants, an equal rise in hemoglobin has been reported.

- Iron polymaltose complex (I-PMC) and carbonyl iron are two moretypes of iron preparations that deserve mention. The bioavailability of iron poly maltose complex (I-PMC) has been demonstrated to be similar to ferrous sulfate. Also, both ferrous sulfate and I-PMC in equivalent doses were found to have similar efficacy in a recent meta-analysis on iron poly maltose complex use in adults with IDA.

- In the case of carbonyl iron, the main advantages are the small particle size of the molecule contributing to increased bioavailability as well as the considerably higher doses of administration. However, this fact needs further research as the result of two Indian studies are conflicting, one stating that the bioavailability to be higher and another study finding the bioavailability to be similar. Carbonyl iron has been mainly used in food fortification industry.

- Conventionally, a dose of 4-6 mg/kg/day of elemental iron was recommended for the treatment of IDA in children. However, it was found that smaller doses were also equally effective as well as better tolerated. Hence, currently, a dose of 3 mg/kg/day of elemental iron is recommended. It is to be noted that approximately 25 mg of elemental iron saturates the absorptive capacity of iron in the duodenum. Therefore, the absorption of iron will not be increased at higher doses.

- Low et al. in a meta-analysis of randomized controlled trials on the effects of daily iron supplementation in 5-12 years old primary school children identified 16501 studies in which a total of 7089 children were evaluated. A total of 31 studies had been conducted in low- or middle-income settings. The review concluded that there was improvement in intelligence quotient (p = 0.04), global cognitive scores (p = 0.01) as well as measures of attention and concentration among anemic children on iron supplementation. [46]
- An improvement in age-adjusted height and weight among anemic children on iron supplementation was also noted. According to this review, the risk of iron deficiency and iron deficiency anemia were 50% and 79% respectively by iron supplementation.
- Desai et al. conducted a study in Western Kenya among children less than 2 years living in a malaria-endemic area, comparing the efficacyof supervised as well as unsupervised, daily and twice weekly iron supplementation over a period of 6 weeks in the treatment of mild and moderate anemia after administering a single dose of sulfadoxine-pyrimethamine at enrollment. Daily supervised or unsupervised iron supplementation was given in the dose of 3–6 mg/kg/day and twice weekly supervised or unsupervised iron supplementation was given in the dose of 6–12 mg/kg/wk. [47]

- Results from the study revealed that hemoglobin concentration in the daily supervised iron supplementation group was significantly higher than twice weekly supervised iron supplementation group. In case of unsupervised iron supplementation groups, hemoglobin concentrations were significantly higher at 12 weeks. But the hemoglobin concentrations were not different at 6 weeks of iron supplementation.

- It was concluded that, in the treatment of anemia in preschool children, regardless of compliance to therapy, hematological responses can be expected after 6 weeks of daily iron supplementation rather than twice weekly iron supplementation.

- A randomized controlled trial titled "Comparison of Therapeutic Efficacy of Ferrous Ascorbate and Iron Polymaltose Complex in Iron Deficiency Anemia in Children" was carried out by Prasanthi Patil et al. In a tertiary care hospital, 125 children aged one to twelve who exhibited clinical symptoms and signs of infectious disease-related illnesses participated in a randomized controlled study (RCT). The subjects were randomized into two groups: FA and IPC. Iron salts (FA or IPC) were administered to both groups at random at a dose of 6 mg/kg elemental iron for three months. Hemoglobin (Hb), mean corpuscular volume (MCV), red cell distribution width (RDW), and reticulocyte count were measured on days three and seven, after one month and three months. After three months of intervention, they documented improvements in hematological markers for both groups.

- The rise in Hb (g%) at 3 mo in the FA group (4.88 ± 1.28) vs. IPC group (3.33 ± 1.33); p = 0.001 and at the end of 1 mo in the FA group (3.13 ± 1.01) vs. IPC group (2.0 ± 0.85); p = 0.017 showed a statistically significant difference.. ANOVA revealed that FA had a substantially better rise in mean Hb than the IPC group F [3392] = 1.79; p = 0.00. There was a statistically significant difference in the mean increase in MCV (fL) between the FA group (6.71 ± 8.32) and IPC group (2.91 ± 6.16); p = 0.011, and between the FA group (9.80 ± 8.56) and IPC group (5.35 ± 6.11); p = 0.004. The statistical significance was observed in the mean decrease in RDW (%) at 1 mo in the FA group (4.23 ± 3.27) compared to

the IPC group (2.67 ± 1.95); p = 0.005 and at 3 mo in the FA group (5.74 ± 3.63) compared to the IPC group (4.04 ± 2.17); p = 0.006. The mean reticulocyte count increased differently in the FA group (0.88 ± 0.50) compared to the IPC group (0.43 ± 1.20); p = 0.017, and in the FA group (4.00 ± 1.69) compared to the IPC group (2.19 ± 1.24); p = 0.001; both differences were statistically significant. ANOVA yielded F [2294] = 29.2, p = 0.00. Over the course of the trial, the IPC group had no adverse reactions, whereas the FA group had some.

- They came to the conclusion that over the three months of the intervention, the hematological parameters significantly improved when both iron salts—FA and IPC—used to treat IDA exhibited statistically significant improvement. Compared to IPC, patients on FA supplements showed greater improvement in hematological markers. [48]

- Sutapa Ganguly et al., had done a study on Comparison between Ferrous Ascorbate and Colloidal Iron in the Treatment of Iron Deficiency Anemia in Children from Kolkata, India. They reported that Out of the 137 children screened, 80 were included in the analysis. The mean rise in hemoglobin at the end of the 12 weeks was significantly higher in ferrous ascorbate group than the colloidal iron group [3.24 ± 1.66 gm% vs. 1.42 ± 2.04 gm%; p<0.01]. After 12 weeks of therapy, the ferrous ascorbate group had a responder rate (hemoglobin ≥11.5 gm%) of 53.57%, while the colloidal iron group had a responder rate of 10.34%; p<0.01. The study provides evidence for the role of ferrous ascorbate as an efficient oral iron supplement in the treatment of iron deficiency anemia in children. [49]

- Diksha Asati et al., conducted a study on comparison between oral ferrous ascorbate and colloidal iron in the treatment of iron deficiency anemia. They reported that Hemoglobin (gm%) significantly increased from 7.40 to 12.87 in ferrous ascorbate group and from 7.24 to 11.32 in colloidal iron group at the end of 12 weeks of treatment ($p<0.05$). There was a significant increase in corrected reticulocyte count (%) from 0.52 to 1.39 in ferrous ascorbate group and from 0.42 to 1.27 in colloidal iron group ($p<0.05$). Serum ferritin (mcg/liter) was also significantly increased from 11.54 to 21.53 in ferrous ascorbate group and from 10.57 to 20.52 in colloidal iron group at the end of 12 weeks ($p<0.05$). they concluded that ferrous ascorbate is an efficient oral iron supplement in the treatment of iron deficiency anemia in the pediatric age group compared to colloidal iron. [50]

- Vijay N et al., conducted a study on the Treatment of Iron Deficiency Anemia in Children: Comparative Study of Ferrous Ascorbate and Colloidal Iron. They reported that out of 81 children screened, 73 were included in the study. The mean rise in Hb at the end of the 12 wk was significantly higher in ferrous ascorbate group than the colloidal iron group [3.59±1.67 g/dl vs. 2.43± 1.73 g/dl; $P<0.01$]. Significantly higher proportion of children receiving ferrous ascorbate (64.86 % vs. 31.03 %; $P<0.01$) became non-anemic in comparison to colloidal iron. Compared to colloidal iron, ferrous ascorbate raises hemoglobin levels noticeably more. The research demonstrates that ferrous ascorbate is an effective oral iron supplement for treating iron deficiency anemia, hence supporting its usage in young patients. [51]

MATERIALS AND METHODS

This is a Randomized control trial study conducted at KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, for a period of 1 year from April 2023 to March 2024.

Study Design: Interventional study (Randomized control trial)

Study Period: One Year (April 2023 to March 2024)

Study Setting: Children aged 1-18years attending in-patient and out-patient Department in

KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

Ethical considerations:

- Prior approval from the Institutional Ethics Committee has been obtained.
- All the participants in this study are Voluntarily involved
- Informed consent was taken from every participant's guardian.
- Participant confidentiality will be maintained.
- Participants were not subjected to any potential harm.

Inclusion Criteria:

- Children aged between 1-18years of age (Inpatient & Outpatient)
- WHO hemoglobin thresholds used to define anemia in different age groups are children 6 months to 5 years: 11 g/dl; children 5–12 years: 11.5 g/dl; children 12-18 years:12g/dl.

- The WHO criteria proposed to define depleted storage iron are 12µg/L for children -under 5 years and 15µg/L for those over 5 years, higher threshold of 30µg/L is used in the presence of infection or inflammation.

Exclusion criteria:

- Children aged less than 1 year of age group.
- Children with chronic debilitating disease.
- Children who are already on iron supplementation.
- Children with severe anemia who require parenteral iron supplementation.

Sample Size:

The formula used for sample size calculation is,

$$n = \left[\frac{(Z_{\alpha/2} + Z_{\beta})}{[F(Z_0) + F(Z_1)]}\right]^2$$

where µi is mean of ith group, µj is mean of jth group, σ^2 is the common error variance, Z(1- ∝/(2*k))is Z score adjusted for α level of significance (Bonferroni Correction), k is the number of pairwise comparisons and Z_(1-β) value is Z score for (1-β) % power.

Assuming between group effect size to be 0.4, at 5% level of significance, and 80% power, the sample size is obtained to be 44 subjects for each group. Hence, total sample size required is 44 x 2 = 88 subjects.

Considering a 10% follow-up loss, the sample size will be 49 subjects for each group. The total sample size required is 49 x 2 = 98 subjects. As the sample size increases, the accuracy of the result also increases.

Study Tools:

Complete Blood Count- Hb(gm/dl), MCV, MCH, MCHC, Serum Iron, Serum Ferritin, Trans sat, RC (%), TIBC

Procedure of Data Collection:

It is a randomized control trial study to be done in KLE'S Dr Prabhakar Kore Hospital & Research Centre including children of age group between 1 year to 18 years diagnosed with Iron deficiency anemia.

Children who meet the eligibility criteria will be enrolled into the study after obtaining written informed consent from parents. data will be recorded in a structured proforma. Detailed information will be collected. Blood samples will be drawn. Based on Hemoglobin, RBC Indices, peripheral smear, reticulocyte count and iron studies values children within the treatment range of anemia will be divided into 2 groups based on the computer-based tablet method to either of 2 groups:

Group 1: Patients who receive ferrous ascorbate syrup(30mg/5ml) in one or two divided doses a day for 3 consecutive months.

Group 2: Patients who receive ferrous sulfate tablets (in drug-divided dosages) in one or two divided doses a day for 3 consecutive months.

Standard Treatment will be initiated in all patients after being randomly assigned to a group& will be continued for a period of 3 months with a dosage of 6mg/kg b.wt.

Then iron preparations with ferrous ascorbate, and ferrous sulfate (which are prepared in similar types of bottles with equal composition) will be given respectively for 3 months. Here group receiving ferrous sulfate will be taken as controls and the group receiving ferrous ascorbate as tests and assessment of treatment will be done by clinical findings of the patient by the end of 1 month and follow-up investigations with hemoglobin, RBC Indices, peripheral smear, reticulocyte count and iron studies will be done at end of a 3-month course of treatment and results to be assessed based on the study reports.

Statistical Analysis:

Patients' data was collected in predesigned proforma. Data shall be analyzed using SPSS 23.0 was used for the analysis and evaluation of the data, and Microsoft Word and MS Excel have been used to generate graphs, tables, etc. Mean and standard deviation (SD) were computed for quantitative data, whereas percentages were computed for qualitative data. A chi-square test was utilized to compare the variations amongst categorical variables. The Wilcoxson matched test and the student's t-test were used to compare the means. For interpretation of results, significance shall be adopted at p-value < 0.05 at a 95% confidence interval.

RESULTS

Table 8: Age category

Age Category	Frequency	Percentage
< 5 years	61	62.2
11-18 years	17	17.3
6-10 years	20	20.4
Total	98	100.0

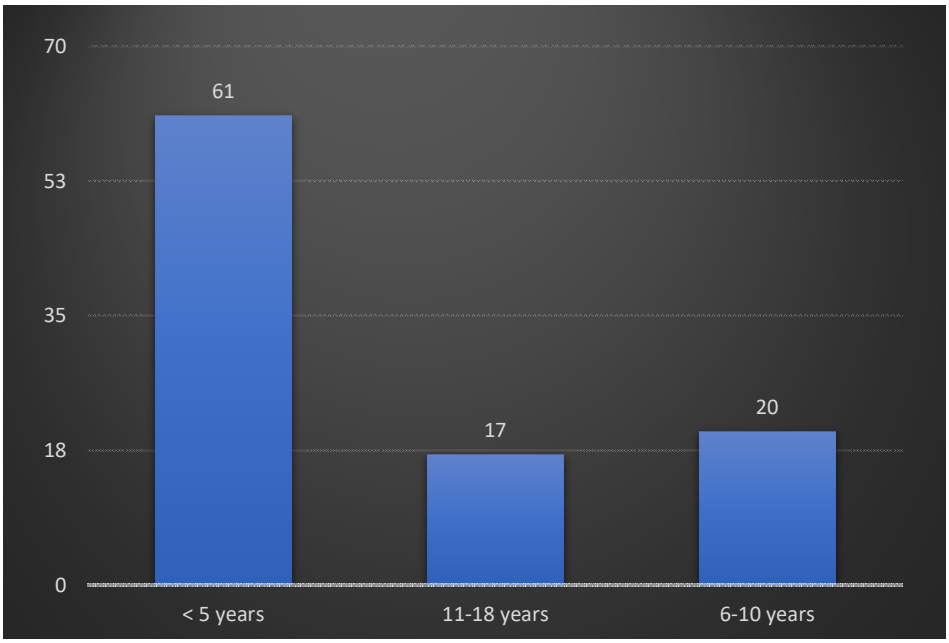


Figure 5 Bar diagram- trends in Age distribution

Table 9: Gender

Gender	Frequency	Percentage
Female	40	40.8
Male	58	59.2
Total	98	100.0

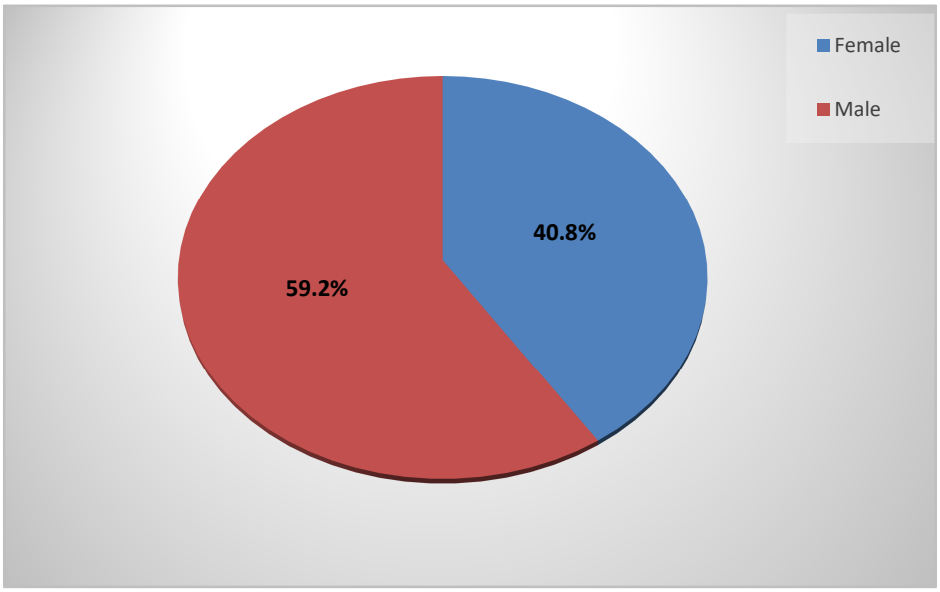


Figure 6 Pie diagram- trends in Gender distribution

Table 10: Age category and study groups.

Age Category	F ascorbate	F sulfate	Total
< 5 years	37 (60.7%)	24 (39.3%)	61 (62.2%)
11-18 years	3 (17.6%)	14 (82.4%)	17 (17.3%)
6-10 years	6 (30%)	14 (70%)	20 (20.4%)
Total	46 (46.9%)	52 (53.1%)	98 (100%)

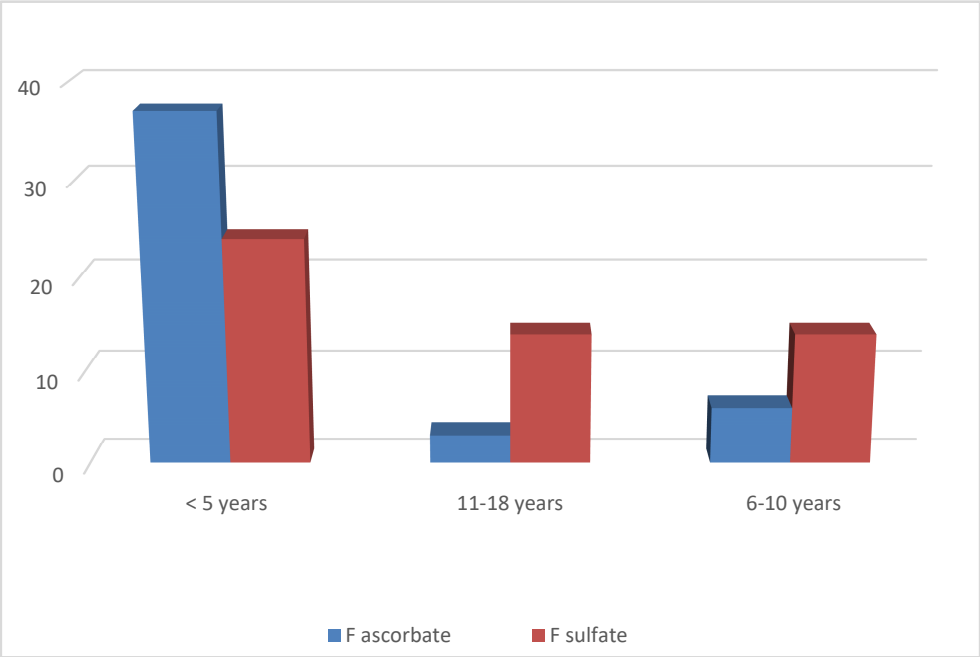


Figure 7. Bar diagram- trends in Age category and study groups in current study

Table 11: Gender and study groups

Gender	F ascorbate	F sulfate	Total
Female	21 (52.5%)	19 (47.5%)	40 (40.8%)
Male	25 (43.1%)	33 (56.9%)	58 (59.2%)
Total	46 (46.9%)	52 (53.1%)	98 (100%)

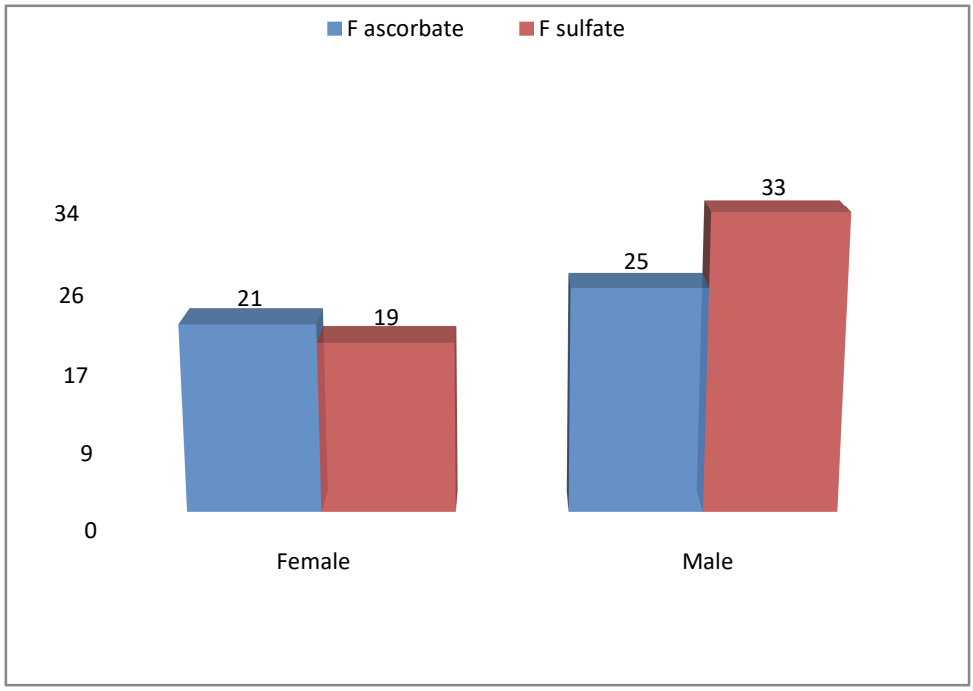


Figure 8. Bar diagram- trends in Gender category and study groups in current study

Table 12: Baseline characteristics of the study population

Parameters	F. Sulfate	F. Ascorbate	P value
Age	7.31 ± 3.67	7.21 ± 4.62	0.217
Hb(gm/dl)	9.15 ± 1.21	9.36 ± 1.06	0.453
MCV	65.6±6.91	68.19 ± 4.97	0.485
MCH	19.93±3.7	21.21 ± 2.31	0.065
MCHC	28.67 ± 1.78	28.71 ± 1.93	0.482
S Iron	35.5±19.47	30.26 ± 15.95	0.854
S Ferritin	14.19±30.31	13.90 ± 14.44	0.117
Trans sat	7.47±4.91	8.89 ± 5.99	0.055
RC (%)	1.32±0.52	1.23 ± 0.57	0.175
TIBC	422.97±58.6	401.82 ± 59.31	0.747

Table 13: Baseline characteristics of study population before and after the intervention

Parameters	F. Sulfate	F. Ascorbate	
Hb(gm/dl)			<0.001
Before	9.15 ± 1.21	9.36 ± 1.06	
After	11.87±0.92	12.25 ± 0.75	
MCV			<0.001
Before	65.6±6.91	68.19 ± 4.97	
After	89.1±5.8	89.62 ± 2.74	
MCH			<0.001
Before	19.93±3.7	21.21 ± 2.31	
After	29.31±3.12	29.75 ± 1.54	
MCHC			<0.001
Before	28.60 ± 1.78	28.71 ± 1.93	
After	33.63 ± 1.51	34.02 ± 1.35	
S Iron			<0.001
Before	35.5±19.47	30.26 ± 15.95	
After	77.1±26.72	80.88 ± 29.45	
S Ferritin			<0.001
Before	14.19±30.31	13.90 ± 14.44	
After	102.05±75.03	109.61 ± 55.62	
Trans sat			<0.001
Before	7.47±4.91	8.89 ± 5.99	
After	34.65±3.92	35.32 ± 2.43	
RC (%)			<0.001
Before	1.32±0.52	1.23 ± 0.57	
After	0.97±0.24	0.95 ± 0.32	
TIBC			<0.001
Before	422.97±58.6	401.82 ± 59.31	
After	314.8±18.22	312.12 ± 15.97	

Table 14: Adverse Effects and Study Groups

Adverse Effects	F. Sulfate	F. Ascorbate
N & V	4	1
Metallic taste	6	0
Heartburn	1	0
Constipation	5	3
Diarrhea	5	2
Black tarry stool	7	3
Staining of teeth	5	0
Flushing	1	0
Fever	2	3
Headache	1	0

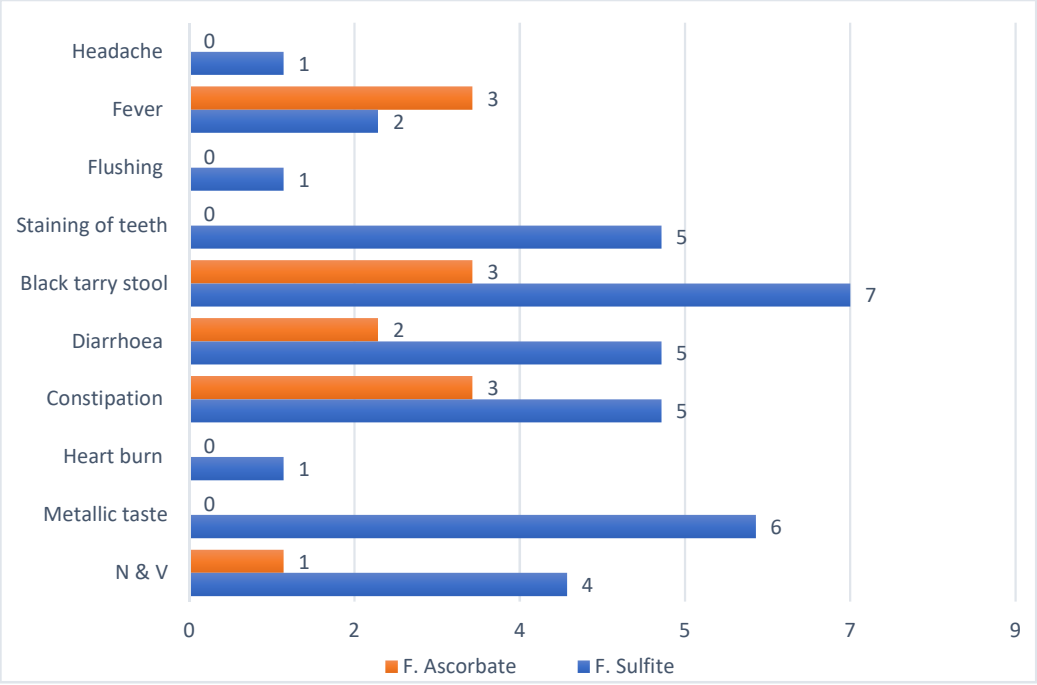


Figure 9. Bar diagram- trends in adverse effects and study groups in current study

DISCUSSION

Anemia is a worldwide health concern that is particularly common in young children. Children can be impacted by anemia in various ways. Children who are anemic have poor development and growth. Low iron levels cause cognitive and psychomotor impairment as well as subpar academic performance. It has been demonstrated that the iron deficiency-related deficit is irreversible. [Lozoff]

The current study was conducted to compare the efficiency of oral iron preparations, like ferrous ascorbate and ferrous sulfate in children aged between 1-18 years of age group. A total of 98 children were included and were grouped into two, one group will get Ferrous Ascorbate and another will get Ferrous Sulfate.

AGE:

In our study, 62.2% of children belonged to less than 5 years of age followed by 20.4% in 6-10 years and 7.3% in 11-18 years age group. The mean age of the children was 5.45 ± 4.56. the mean age of Ferrous Ascorbate group was 7.21 ± 4.62 and ferrous sulfate group was 7.31 ± 3.67. Between the groups, there was no statistically significant difference.

Ganguly et al., conducted a study on 80 children. The mean age of Ferrous ascorbate was 5.91 ± 3.73 and Colloidal iron was 4.37 ± 2.91. They ranged between 0.5-12 years in ferrous ascorbate group and 0.58-10 for colloidal group.

Yewale et al., conducted a study on 77 children. The mean age of the children was 2.05±2.33 for Ferrous ascorbate group and 2.72±2.83 for colloidal iron. They

ranged between 0.5-12 years in ferrous ascorbate group and 0.5-12 for colloidal group.

Asati D et al., conducted a study on 50 children. The mean age of Ferrous ascorbate group was 4.21 ± 1.47 and for Colloidal iron group was 3.98 ± 1.24. They ranged between 0.5-12 years in ferrous ascorbate group and 2-12 in colloidal group.

Prashant P et al., conducted a Randomised control trial to compare the efficacy of two salts. The mean age of ferrous ascorbate was 3.01 ± 2.16, and the mean age of Iron poly maltose complex was 2.31 ± 1.29.

Table 15: Age distribution and study groups across different studies

Study	Ferrous Ascorbate	Ferrous Sulfate	Colloidal iron
Ganguly et al.,	5.91 ± 3.73	-	2.72±2.83
Yewale et al.,	2.05±2.33	-	2.72±2.83
Asati D et al.,	4.21 ± 1.47	-	3.98 ± 1.24
Prashant P et al.,	3.01 ± 2.16	-	2.31 ± 1.29 (IPC)
Current study	5.45 ± 4.56	7.21 ± 4.62	-

GENDER:

In our study, 58 (59.2%) of children were males and 40 (40.8%) were females. There are 21 females and 25 males in Ferrous ascorbate group whereas, 19 were females and 33 were males in ferrous sulfate group.

In a study by Ganguly et al., There were 13 females and 28 males in Ferrous ascorbate group whereas, 15 were females and 24 were males in Colloidal iron group.

In a study by Yewale et al., There were 15 females and 25 males in Ferrous ascorbate group whereas, 16 were females and 17 were males in Colloidal iron group.

In a study by Asati D et al., There were 12 females and 13 males in Ferrous ascorbate group whereas, 11 were females and 14 were males in Colloidal iron group.

In a study by Prasanth P et al., There were 26 females and 24 males in Ferrous ascorbate group whereas, 25 were females and 25 were males in Iron polymaltose complex group.

Table 16: Gender distribution and study groups across different studies

Study	Ferrous Ascorbate (F/M)	Ferrous Sulfate (F/M)	Colloidal iron (F/M)
Ganguly et al.,	13/28	-	15/24
Yewale et al.,	15/25	-	16/17
Asati D et al.,	12/13	-	11/14
Prashant P et al.,	26/24	-	25/25
Current study	21/25	19/33	-

BASELINE HAEMATOLOGIAL VARIABLES:

In our study, the mean hemoglobin in ferrous Sulfate group was 9.15 ± 1.21 and in ferrous Ascorbate group, it was 9.36 ± 1.06. we compared the MCV, MCH, MCHC, Serum Iron, Serum Ferritin, Trans sat, RC and TIBC of two groups. We observed there was no statistically significant difference observed between the two groups.

We observed the same values as the study subjects of Ganguly S et al., and we observed that mean Hb, MCV, MCH, and MCHC were lower than our study and RC was higher than our study subjects.

In the below table, we compared the hematological parameters between Ganguly S et al., study and the current study.

Table 17: Correlation of hematological parameters between Ganguly S et al., study and current study

	Current study		**Ganguly S et al.,**	
Parameters	F. Ascorbate	F. Sulfate	F. Ascorbate	Colloidal Iron
Hb(gm/dl)	9.36 ± 1.06	9.15 ± 1.21	7.53 ± 1.68	7.68±2.18
MCV	68.19 ± 4.97	65.6±6.91	62.17 ± 6.42	70.05 ± 11.94
MCH	21.21 ± 2.31	19.93±3.7	16.01± 3.04	17.96 ± 5.17
MCHC	28.71 ± 1.93	28.67 ± 1.78	25.69± 3.38	25.28 ± 4.05
S Iron	30.26 ± 15.95	35.5±19.47	-	-
S Ferritin	13.90 ± 14.44	14.19±30.31	-	-
Trans sat	8.89 ± 5.99	7.47±4.91	-	-
RC (%)	1.23 ± 0.57	1.32±0.52	1.36±1.67	0.99±1.42
TIBC	401.82 ± 59.31	422.97±58.6	-	-

In a study by Asati D et al., all the hematological variables were lower than the current study.

In the below table, we compared the hematological parameters between the Asati D et al., study and the current study.

Table 18: Correlation of hematological parameters between Asati D et al., Prashant et al., study and current study

	Current study		**Asati D et al.,**	
Parameters	F. Ascorbate	F. Sulfate	F. Ascorbate	Colloidal Iron
Hb(gm/dl)	9.36 ± 1.06	9.15 ± 1.21	7.40±1.07	7.23±1.39
MCV	68.19 ± 4.97	65.6±6.91	62.92±1.87	64.31±1.48
MCH	21.21 ± 2.31	19.93±3.7	15.64±1.96	18.7±2.95
MCHC	28.71 ± 1.93	28.67 ± 1.78	25.27±1.92	26.5±2.03
S Iron	30.26 ± 15.95	35.5±19.47	-	-
S Ferritin	13.90 ± 14.44	14.19±30.31	11.54±0.25	10.56±0.26
Trans sat	8.89 ± 5.99	7.47±4.91	-	-
RC (%)	1.23 ± 0.57	1.32±0.52	0.52±0.08	0.42±0.08
TIBC	401.82 ± 59.31	422.97±58.6	-	-

In a study by Prashant P et al., Hb and MCV before starting the study were low when compared with our study subjects.

In the below table, we compared the hematological parameters between the Prashant P et al., study and the current study.

Table 19: Correlation of hematological parameters between Prashant et al., study and current study

	Current study		**Prashant P et al.,**	
Parameters	F. Ascorbate	F. Sulfate	F. Ascorbate	IPC
Hb(gm/dl)	9.36 ± 1.06	9.15 ± 1.21	6.85 ± 1.23	6.93 ± 1.38
MCV	68.19 ± 4.97	65.6±6.91	59.38 ± 7.80	59.83 ± 7.31

STUDY VARIABLES AFTER INTERVENTION:

In our study, we compared all the baseline parameters with the same parameters at the end of the intervention. There was no strong statistically significant difference observed between groups.

Table 20: Baseline characteristics of study population before and after intervention

Parameters	F. Sulfate	F. Ascorbate	
Hb(gm/dl)			<0.001
Before	9.15 ± 1.21	9.36 ± 1.06	
After	11.87±0.92	12.25 ± 0.75	
MCV			<0.001
Before	65.6±6.91	68.19 ± 4.97	
After	89.1±5.8	89.62 ± 2.74	
MCH			<0.001
Before	19.93±3.7	21.21 ± 2.31	
After	29.31±3.12	29.75 ± 1.54	
MCHC			<0.001
Before	28.60 ± 1.78	28.71 ± 1.93	
After	33.63 ± 1.51	34.02 ± 1.35	
S Iron			<0.001
Before	35.5±19.47	30.26 ± 15.95	
After	77.1±26.72	80.88 ± 29.45	
S Ferritin			<0.001
Before	14.19±30.31	13.90 ± 14.44	
After	102.05±75.03	109.61 ± 55.62	
Trans sat			<0.001
Before	7.47±4.91	8.89 ± 5.99	
After	34.65±3.92	35.32 ± 2.43	
RC (%)			<0.001
Before	1.32±0.52	1.23 ± 0.57	
After	0.97±0.24	0.95 ± 0.32	
TIBC			<0.001
Before	422.97±58.6	401.82 ± 59.31	
After	314.8±18.22	12. ± 15.97	

Sutapa Ganguly et al., conducted a study on Comparison between Ferrous Ascorbate and Colloidal Iron in the Treatment of Iron Deficiency Anemia in Children from Kolkata, India. They reported that Out of the 137 children screened, 80 were included in the analysis. The mean rise in hemoglobin at the end of the 12 weeks was significantly higher in ferrous ascorbate group than colloidal iron group [3.24 ± 1.66 gm% vs. 1.42 ± 2.04 gm%; $p<0.01$]. After 12 weeks of therapy, the ferrous ascorbate group had a responder rate (hemoglobin ≥11.5 gm%) of 53.57%, while the colloidal iron group had a responder rate of 10.34%; $p<0.01$. The study offers proof that ferrous ascorbate, an effective oral iron supplement, can help treat children's iron deficiency anemia.

In a study by Prasanthi Patil et al., They reported that Both groups had an improvement in hematological parameters at 3 mo of intervention. There was a statistically significant difference in the rise of Hb (g%) at 3 mo in the FA group (4.88 ± 1.28) vs. IPC group (3.33 ± 1.33); $p = 0.001$ and at the end of 1 mo in the FA group (3.13 ± 1.01) vs. IPC group (2.0 ± 0.85); $p = 0.017$. ANOVA revealed that FA had a substantially better rise in mean Hb than the IPC group $F [3392] = 1.79$; $p = 0.00$. There was a statistically significant difference in the mean increase in MCV (fL) between the FA group (6.71 ± 8.32) and IPC group (2.91 ± 6.16); $p = 0.011$, and between the FA group (9.80 ± 8.56) and IPC group (5.35 ± 6.11) at one month; $p = 0.004$. The statistical significance was observed in the mean decrease in RDW (%) at 1 mo in the FA group (4.23 ± 3.27) compared to the IPC group (2.67 ± 1.95); $p = 0.005$ and at 3 mo in the FA group (5.74 ± 3.63) compared to the IPC group (4.04 ± 2.17); $p = 0.006$. The difference in the rise in mean reticulocyte count at day 3 in FA group (0.88 ± 0.50) vs. IPC group (0.43 ± 1.20); $p = 0.017$ and at day 7 in FA group (4.00 ± 1.69) vs. IPC group (2.19 ± 1.24); $p = 0.001$ was statistically significant. F

[2294] = 29.2, p = 0.00 (ANOVA). The FA group experienced mild adverse responses over the trial period, while the IPC group did not have any. They came to the conclusion that over the three months of the intervention, the hematological parameters significantly improved when both iron salts—FA and IPC—used to treat IDA exhibited statistically significant improvement. Compared to IPC, patients on FA supplements showed greater improvement in hematological markers.

Asati D et al., reported that Hemoglobin (gm%) significantly increased from 7.40 to 12.87 in ferrous ascorbate group and from 7.24 to 11.32 in colloidal iron group at the end of 12 weeks of treatment ($p<0.05$). There was a significant increase in corrected reticulocyte count (%) from 0.52 to 1.39 in ferrous ascorbate group and from 0.42 to 1.27 in colloidal iron group ($p<0.05$). At the conclusion of 12 weeks, serum ferritin (mcg/liter) increased considerably ($p<0.05$) in the ferrous ascorbate group from 11.54 to 21.53 and in the colloidal iron group from 10.57 to 20.52. Compared to colloidal iron, they found that ferrous ascorbate is a more effective oral iron supplement for treating iron deficiency anemia in children.

Vijay N et al., reported that the mean rise in Hb at the end of the 12 wk was significantly higher in ferrous ascorbate group than the colloidal iron group [3.59±1.67 g/dl vs. 2.43± 1.73 g/dl; $P<0.01$]. Significantly higher proportion of children receiving ferrous ascorbate (64.86 % vs. 31.03 %; $P<0.01$) became non-anemic in comparison to colloidal iron. Compared to colloidal iron, ferrous ascorbate raises hemoglobin levels noticeably more. The research demonstrates that ferrous ascorbate is an effective oral iron supplement for treating iron deficiency anemia, hence supporting its usage in young patients.

ADVERSE EFFECTS:

In our study, the most common adverse effect observed in ferrous sulfate group was black tarry stools in 7 (13.4%), metallic taste in 6 (11.5%) children, diarrhea, constipation and staining of teeth each in 5 (9.6%) children. The other adverse effects are vomiting in 4 (7.7%) children, Fever in 2 (3.8%), headache in 1 (1.9%), and flushing in one child.

Adverse effects were less observed in the ferrous ascorbate group and they were constipation in 3 (6.5%), Black tarry stool in 3 (6.5%), fever in 3 (6.5%), diarrhea in 2 (4.3%) and nausea and vomiting in 1 (2.1%) children.

Yewale et al., reported that both the study groups were well tolerated. When their children were treated with either iron formulation, no parent reported any major side events. Out of the 150 patients, 74 reported unpleasant effects; however, none of the ptients experienced a significant adverse event, according to Chavan S et al.

The number of patients with adverse effects from group, IPC group and FeA group was 31 (62%), 23 (46%) and 21 (42%), respectively. Among all the groups, nausea was the most frequently reported side effect, occurring in 43 out of 150 participants.

In general, the three most frequent side effects were nausea, epigastric discomfort, and constipation, which were ranked in descending order by stomach pain, diarrhea, and vomiting. However, these side effects were noted with all three of the prescribed drugs. With the exception of epigastric pain, the FS group experienced more side effects than the other two groups, although there was no discernible difference. Epigastric pain was significantly higher in the FS group as compared to

the other two groups (P <0.05). Of the 150 patients, 34 experienced epigastric pain (15 in the FS group, 10 in the IPC group, and 9 in the FeA group; P<0.05). The negative effects were similar in the IPC and FeA groups. According to Asati D et al., the ferrous ascorbate group experienced greater adverse effects than the colloidal iron group. Common adverse effects included constipation, nausea, vomiting, diarrhea, and gastritis. They reported that there was a significant difference in the occurrence of Adverse effects in both groups w.r.t Diarrhea, Nausea and Vomiting, Constipation and Gastritis.

Prasanth P et al reported that the FA group had minor adverse reactions whereas the IPC group had none.

According to a Kanchana et al. study, diarrhea was the main symptom linked to anemia in more than half of the cases examined, and 77.8% of children under the age of five had anemia. According to the [Kanchana] Saba et al study, 72.79% of children under the age of five have anemia. [Saba]. The most common causes of anemia in children between the ages of two and six are milk protein intolerance from cow's milk, delayed weaning, insufficient intake, recurrent infections, and increased demand.

According to the results of the current study, the ferrous sulfate group showed more metallic taste and tooth discolouration than the ferrous ascorbate group. There was a statistically significant difference. After analyzing the tolerability of various iron supplements through a systematic review, Cancelo Hidalgo et al. came to the conclusion that ferrous sulfate with mucoproteose is the best-tolerated iron preparation because it has the lowest incidence of side effects. [Cancelo] According to a study by Azza et al., the iron bisglycinate group experienced fewer side effects

than the iron multi-amino acid chelate and ferrous fumarate groups, which included nausea, vomiting, constipation, and abdominal pain. However, there was no statistically significant difference. [Azza] According to Gupta et al., ferrous sulphate caused the most side effects (52.31%), followed by ferrous ascorbate (45%) and colloidal iron (21%). [Gupta] When Panicker et al. compared the safety and efficacy profiles of ferric ammonium citrate, ferrous fumarate, ferrous sulphate, and ferric calcium citrate, they discovered that there was no discernible difference in either group's efficacy or safety. [Pancker] Iron preparations can have dose-dependent adverse effects. In order to minimize the gastrointestinal adverse effects, it is recommended that iron be taken with a small meal. The slower release of iron from the stable IPC complex may be the cause of the difference in the safety profile between ferrous salt and IPC. [Geisser]

The most common complaints among study participants were constipation and dark stools, followed by nausea, vomiting, gastritis, and metallic taste. Ferrous fumarate was associated with the highest number of adverse events (AEs), followed by ferrous sulfate (40 AEs), ferrous bisglycinate (26 AEs), ascorbate (18 AEs), and sodium feredetate (10 AEs). The bulk of the events reported by Langstaff et al. [Langstaff] were of a gastrointestinal nature: 11% of the standard FS group reported constipation, and 18% reported abdominal pain. Similar findings were reported by Mistry N et al. [Mistry], who found that nausea (31.9%) was the most common side effect, followed by constipation (27.6%) and heartburn (25.5%). Some were less common, such as headaches, nausea, metallic tastes, and epigastric pain.

Ferrous ascorbate's superior safety, tolerability, and efficacy can be attributed to its chemical state, which includes improved iron bioavailability and utilization. Iron is absorbed as much as possible in the ascorbate preparation because of three

factors: inhibition of the formation of insoluble iron complexes that obstruct absorption; inhibition of the effect of phytates, phosphates, and oxalates on iron absorption; and inhibition of the conversion of ferrous into ferric ions, which improves absorption. [Tolkien Z, habib]

Compared to other forms of iron salts, this one has superior absorption, produces fewer free radicals, and prevents the conversion of ferrous to ferric state, all of which contribute to its better tolerability. Less gastrointestinal adverse effects result in the end of this. It can be administered with meals if it is still intolerable.

Tolerability and adherence to the treatment are just as crucial to the management of IDA as the iron salt's bioavailability and effectiveness. The most frequent side effects noted in this study were abdominal pain, constipation, diarrhea, vomiting, and epigastric pain. With the exception of epigastric pain, which was more prevalent in the FS group, there were no major adverse events, and all other side effects were similar across the three study groups. Although attempts to increase gastrointestinal tolerance using various forms of iron preparations, such as FeA, have only marginally improved gastrointestinal tolerance, prior research has also demonstrated that FS is linked to a higher incidence of gastrointestinal adverse effects [Mehta, Duque, berber]. FeA, which contains iron in ferric form, has been observed to have less detrimental effects on the gastrointestinal tract because it does not produce reactive oxygen species [van den Brock]. In contrast to FS, patients treated with FeA experienced fewer side effects and higher compliance, according to a study by Saha et al. [Seha] on anemic pregnant women. Comparably, FeA is recognized to have better compliance and fewer negative effects than FS.

CONCLUSION

- The mean age of the Ferrous Ascorbate group was 7.21 ±4.62 years and the ferrous sulfate group was 7.31 ±3.67 years. no statistically significant difference was observed between the groups.

- No Statistically significant difference in the rise in Hemoglobin levels among both groups ($p < 0.001$)

- No Statistically significant difference in the rise in ferritin levels among both groups ($p < 0.001$)

- No Statistically significant difference in the rise in serum iron levels among both groups ($p < 0.001$)

- The most common adverse effect observed in the ferrous sulfate group was black tarry stools in 7 (13.4%), metallic taste in 6 (11.5%), diarrhea, constipation, and staining of teeth in 5 (9.6%) children.

- Adverse effects in the ferrous ascorbate group were constipation in 3 (6.5%), Black tarry stool in 3 (6.5%), fever in 3 (6.5%), diarrhea in 2 (4.3%) and nausea and vomiting in 1 (2.1%) children.

- Overall Therapeutic effect of both salts is similar and statistically nonsignificant difference

- Overall Adverse effects were less observed in the ferrous ascorbate group compared to ferrous sulfate

SUMMARY

RECOMMENDATIONS

This study showed that both iron salts are equally efficacious in terms of treating Iron Deficiency Anemia in children aged between 1-18 years; however, due to its better compliance and lesser adverse effects Ferrous Ascorbate has better tolerance than Ferrous Sulfate.Due to fewer adverse effects compliance and adherence to treatment can be greatly improved with ferrous ascorbate

LIMITATIONS

This study was limited by the small sample size of 98 children; additional information is needed to completely comprehend the efficacy and safety of these iron preparations.

This study's three-month duration was another limitation; further research on the long-term negative consequences of these iron preparations would need to be done with a longer study period and prospective follow-up.

The single-blinded research design was another disadvantage since it could have caused bias in the gathering or analysis of side-effect data. More illuminating information on the medication's safety could have been obtained from double- or triple-blind research.

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ANNEXURE – 1

INFORMED CONSENT FORM

"COMPARING EFFICIENCY OF FERROUS SULFATE AND FERROUS ASCORBATE IN TREATMENT OF IRON DEFICIENCY ANEMIA IN CHILDREN AGED BETWEEN 1-18YEARS OF AGE GROUP –A RANDOMIZED CONTROL TRIAL ``

Principle Investigator:.

Co-investigator

Objective:

To compare the efficiency of : oral iron preparations ferrous ascorbate,ferroussulfate in treatment of iron deficiency anemia in children aged between 1-18 yrs of age group

Introduction:

According to the most recent Demographic and Health Survey (DHS) and the Multiple Indicators Cluster Survey (MICS), the prevalence of anemia among children aged < 5 years in the Democratic Republic of Congo (DRC) is around 63%.In south east asia the prevalence of anemia ranges from 45-55% in children less than 12 years. Maintaining a normal iron balance in these settings is challenging, as iron-rich foods with good bioavailability are of animal origin and expensive not affordable by most of the population.

Hence this study will be carried out to check this association

Explanation of procedure

Based on Hemoglobin,RBC Indices, peripheral smear reticulocyte count and iron studies values children within treatment range of anemia will be devided into 2 groups based on lottery method. Then iron preparations with ferrous ascorbate, ferroussulfate will be given respectively for 3 months here group receiving ferrous sulfate will be taken as controls and group receiving ferrous ascorbate as tests and follow up investigations with hemoglobin, RBC Indices, peripheralsmear,reticulocyte count and iron studies will be done at end of 3 month course of treatment and results to be assessed based on the study reports

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups.

However, your identity will never be revealed.

Questions: If you have any question or complaints with regard to your right as study participant you may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study ***"COMPARING EFFICIENCY OF FERROUS SULFATE AND FERROUS ASCORBATE IN TREATMENT OF IRON DEFICIENCY ANEMIA IN CHILDREN AGED BETWEEN 1-18YEARS OF AGE GROUP –A RANDOMIZED CONTROL TRIAL"***. My signature below indicates that I have decided to participate/let my child participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the child:

Age of the child:

Signature or left thumb impression of the child (If >12years):

Verbal consent from child(7-12years):

Name of the Parent/Guardian:

Signature or left thumb impression of the Parent/Guardian:

Name of the investigator:

Signature of the investigator:

ANNEXURE-II

PROFORMA

"COMPARING EFFICIENCY OF FERROUS SULFATE AND FERROUS ASCORBATE IN TREATMENT OF IRON DEFICIENCY ANEMIA IN CHILDREN AGED BETWEEN 1-18YEARS OF AGE GROUP –A RANDOMIZED CONTROL TRIAL ``

Overall Serial No:

IP Number:

Date:

Socio-demographic Particulars:

Informant's Name:

Relation:

Profession:

Education:

Permanent Residence:

Contact Telephone:

Patient's Name:

Gender: Male/Female

Date of Admission:

Age:

STUDY GROUP(A/B):

	DAYS TAKEN	DAYS SKIPPED
NO OF DAYS TREATMENT WAS TAKEN		

	AT THE TIME OF DIAGNOSIS	AT THE END OF 1 MONTH	AT THE END OF 3 MONTHS
HEMOGLOBIN(gm/dl)			
RETICULOCYTECOUNT			
PERIPHERAL SMEAR			
MCV/MCH/MCHC			
SERUM IRON			
FERRITIN			
TRANSFERRIN			
TIBC			

Duration of hospital stay(if any):

DATE:

PLACE:

During 1st visit(i.e after 1month of treatment duration)

The common complaints the child have come up with during the course of treatment (drug related)

Adverse Effects	**Yes**	**No**
Nausea & Vomitings		
Metallic taste		
Heart burn		
Constipation		
Diarrhoea		
Black Tarry stool		
Staining of Teeth		
Flushing		
Fever		
Headache		

ANNEXURE III-KEY TO MASTERCHART

HB	-	Hemoglobin
RC	-	Reticulocyte count
PS	-	Peripheral smear
MCV	-	Mean corpuscular volume
MCH	-	Mean corpuscular hemoglobin
MCHC	-	Mean corpuscular hemoglobin concentration
TIBC	-	Total Iron binding capacity

ANNEXURE IV- MASTERCHART

S No	OP/IP No	PT Name	Sex	Age	Hb(gm/dl)	RC(%)	PS	MCV	MCH	MCHC	S Iron	S Ferritin	Trans sat	TIBC	Interved with	Hb(gm/dl)	RC (%)	PS	MCV	MCH	MCHC	S Iron	S Ferritin	Trans sat	TIBC	N & V	Metallic taste	Heart burn	Constipation	Diarrhoea	Black tarry stool	Staining of teeth	Flushing	Fever	Headache
1	1181334	Sarvesh	M	6yrs	7.8	0.6	MHA	60.3	16.5	27.3	13	5.07	3	486	F ascorbate	10.2	0.9	NBP	82.5	27.9	33.4	52	24.8	29	302	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
2	1182028	Anvita	F	1.5 yrs	8.7	0.8	MHA	70	20.8	29.8	54	11.13	16	348	F ascorbate	11.6	1.2	NBP	84.1	26	32.4	98	29.4	31	306	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
3	6400644	Aarav	M	1.5 yrs	7.4	0.7	MHA	48.6	12.9	26.5	18	9.86	3	591	F ascorbate	10.2	0.8	MHA	76.2	20.8	29.4	38	36	28	345	NO	NO	NO	NO	NO	2 days	NO	NO	NO	NO
4	6475242	Aryan	M	1.5 yrs	6.6	1.3	MHA	46.1	11.5	25	15	2.96	3	565	F ascorbate	9.8	1	MHA	72.4	21.6	28.6	30	30.6	34	376	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
5	1182612	Md Umar	M	13 months	9.4	0.6	MHA	57.3	16	28	13	9.32	3	430	F ascorbate	10.6	0.7	NBP	85.5	26.6	31.1	43	18.6	28	306	NO	NO	NO	NO	2 days	NO	NO	NO	NO	NO
6	1186831	Umera	F	3.5 Yrs	7.3	1.7	MHA	55.2	16.2	24.9	16	17.5	5	321	F ascorbate	11.2	0.8	NBP	94.2	36.2	34	60	18.6	19	302	2 days	NO	NO	NO	NO	NO	NO	NO	NO	NO
7	1189756	Anushri	F	20 months	6	1.5	MHA	53.4	13.4	25.1	54	10.6	14	359	F ascorbate	9	1.1	MHA	78	24	30.6	64	20.8	36	391	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
8	1191619	Mariyam	F	1.5 yrs	9.3	1	MHA	73.1	21.9	29.9	14	5.6	6	406	F ascorbate	11.8	1.4	NBP	88.6	29.6	33.8	68	32.4	36	326	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
9	1198551	Husman	M	13 months	8.2	1.5	MHA	54.2	13.8	25.4	56	10.4	4	428	F ascorbate	12.9	1	NBP	89.5	31.5	35.2	88	73.6	34	326	NO	NO	NO	2 Days	NO	NO	NO	NO	NO	NO
10	1195650	Krushi	F	16 months	9.8	0.9	MHA	69.2	21.2	30.6	24	10.6	3	486	F ascorbate	11.8	1.1	NBP	81.2	25.3	31.4	54	42.6	39	308	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
11	1149388	Ishika	F	14 months	9.1	1.8	MHA	72.5	26	31.6	16	10.8	6	388	F ascorbate	11.2	0.8	NBP	86.2	24.8	30.2	38	96	34	301	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
12	1198001	Maruthi	M	13 months	10.7	0.9	MHA	72	26.4	28.4	18	29.1	6	398	F ascorbate	12.6	0.6	NBP	90.6	30	32.6	54	64	32	301	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
13	1198943	Kashinath	M	16 months	10.8	1	MHA	70.5	22.4	31.8	66	25.8	3	428	F ascorbate	12.4	1.2	NBP	88.6	28.4	32.6	88.4	29	36	316	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
14	1201763	Samarth	M	3 yrs	11	0.5	MHA	68.5	20.3	29.6	54	11.1	16	348	F ascorbate	13	0.9	NBP	86.6	28	32.8	86	126	34	301	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
15	1201714	Namira	F	1.5 yrs	10.9	1.2	MHA	60	20.8	31.6	60	20.6	22	306	F ascorbate	12.4	1.6	NBP	86	28	32.6	68	86	34	301	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
16	1202124	Asad	M	16 months	10.5	1.2	NBP	70.6	22.4	28	56	26.6	14	448	F ascorbate	12.9	0.8	NBP	90.2	32.6	35.4	108	266	34	332	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
17	1202124	Asad	M	13 months	10.8	1.4	MHA	69	22	30.6	68	29.6	3	318	F ascorbate	13	1	NBP	98	32	34.6	86	92	34	306	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
18	1202532	Divyansh	M	1.5 yrs	8.6	0.6	MHA	54.3	14.1	24.7	17	6.8	4	442	F ascorbate	11.8	0.9	NBP	88.4	29.6	32.6	63	58.4	40	326	NO	NO	NO	NO	NO	NO	NO	NO	1 day	NO
19	1203476	Masood	M	2 yrs	8.5	1	MHA	68	18.9	29.1	16	6.5	6	408	F ascorbate	12.8	0.9	NBP	91.2	31.4	34	64	76	36	301	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
20	1203896	Shriyansh	M	16 months	8.9	0.9	MHA	71	20.8	28	56	10.4	4	428	F ascorbate	11.6	0.6	NBP	88.6	29.2	33.6	60	48	36	328	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
21	1204215	Tanvik	M	13 months	9.2	1	MHA	66	18.9	29	24	10.6	3	486	F ascorbate	11.2	1.6	NBP	88.6	29.8	34.6	85	186	34	310	NO	NO	NO	NO	1 day	NO	NO	NO	NO	NO
22	1202712	Azka	F	2 yrs	10.4	1.2	MHA	71.2	23.3	28.7	32	8	9	328	F ascorbate	12.4	0.8	NBP	90	30.1	34.6	64	96.4	36	326	NO	NO	NO	1 day	NO	NO	NO	NO	NO	NO
23	1203248	Lukman	M	1.6 yrs	10.1	0.1	MHA	71.9	21	29.3	66	24.8	3	448	F ascorbate	11.8	1	NBP	86.4	31	35.8	78	110	46	310	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
24	1204747	Arush	M	3 yrs	10.2	0.9	MHA	67.8	19.7	29.1	68	7.6	4	392	F ascorbate	12.9	1	NBP	94	31	32.8	74	108	36	304	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
25	1205373	Bhavishya	F	2 yrs	8.4	1.4	MHA	57.6	15.3	26.5	32	3.9	7	444	F ascorbate	11.8	1.1	NBP	81.2	25.3	31.4	56	44.8	36	310	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
26	1205911	Vithal	M	1 yr	9.4	0.7	MHA	64.6	18.3	28.3	25	3.8	7	377	F ascorbate	12.6	1.2	NBP	88.4	28.6	32.8	98	30.8	34	301	NO	NO	NO	NO	NO	4 days	NO	NO	NO	NO
27	10000137	Vedant	M	2 yrs	8.8	2.6	MHA	64.6	20.7	26.7	34	4.3	7.2	426	F ascorbate	11	1.4	NBP	88.6	28.4	32.6	86.4	32	34	312	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
28	1208954	B/o Sukanya	F	2 yrs	10.6	1.3	MHA	70.6	24.8	26.6	64	19.4	3	446	F ascorbate	13.6	0.9	NBP	88.6	29	34.6	148	268	36	302	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
29	10004207	Kuldeep singh	M	14 months	7	1.4	MHA	70.1	21.1	30.2	26	1.8	6	506	F ascorbate	11.6	0.9	NBP	86.6	28	32.6	86	124	34	306	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
30	1207121	Hassan	M	6 yrs	9.6	2.1	MHA	66.4	15.8	22/.4	34	3.4	7	468	F ascorbate	12.8	1.6	NBP	95	33.6	38.8	110	224	38	300	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
31	10000860	Vaidehi	F	14 months	9.3	1.8	MHA	65.4	18.2	30.2	16	10.8	4.6	460	F ascorbate	11.8	0.9	NBP	87.6	29.4	33.8	48	122	34	312	NO	NO	NO	NO	NO	NO	NO	NO	1 day	NO
32	1209037	Amruta	F	11 yrs	8.5	1.9	MHA	68	19.6	27.2	28	66.8	6	490	F ascorbate	11.6	0.8	NBP	88	29.6	34.8	68	264	33	320	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
33	10000311	Jamadar	M	15 yrs	8.6	1.3	MHA	62	20.4	28.9	64	190	17	398	F ascorbate	11	0.8	NBP	98	30.6	32.8	80.6	134.4	33	326	NO	NO	NO	NO	NO	4 days	NO	NO	NO	NO

34	10001234	Rohit	M	9 yrs	8.4	1.4	MHA	60.2	18.6	28	34	63.9	7	390	F ascorbate	11.9	1.1	NBP	86.2	26.3	32.4	56	49	34	310	NO	NO	NO	2 Days	NO	NO	NO	NO	NO	NO
35	10000109	Shreya	F	4 yrs	9.2	2	MHA	64.8	20.2	29.6	26	3.9	8	378	F ascorbate	12.4	0.9	NBP	98.4	28.6	33	102	136.8	36	310	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
36	1209229	Renuka	F	5 yrs	9.4	1.6	MHA	69.8	25.4	30.2	22	4	18	430	F ascorbate	11.8	0.9	NBP	90.6	32.4	35	140	168	34	310	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
37	10001138	Harish	M	8 yrs	8.8	1.8	MHA	64.2	15.8	28.4	36	64	8	420	F ascorbate	11.8	1	NBP	90.4	26.8	32.8	64	58.6	33	312	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
38	10000979	Deepa	F	2 yrs	10.6	1.6	MHA	68.6	22.4	32.8	72	8.2	6	420	F ascorbate	12.2	1	NBP	98.2	31.6	36.8	82	126	40	308	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
39	10000971	Advika	F	2 yrs	8.8	1.6	MHA	64.6	23.4	29	62	48	16	408	F ascorbate	11.6	0.8	NBP	98	32.6	34.8	88	76.5	32	308	NO	NO	NO	NO	NO	NO	NO	NO	2 days	NO
40	10000938	Sana	F	6 yrs	10.8	1.8	MHA	70.2	22.8	29.4	20	12	5	398	F ascorbate	12	0.9	NBP	90.8	30.4	35.2	80	160	37	320	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
41	10003433	Tejaswini	F	10 yrs	9.6	2.6	MHA	76.2	24.2	28.6	34	18	7	426	F ascorbate	12.4	1	NBP	98	34.2	39.6	124	256	40	302	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
42	10002472	Tarbez	M	2 yrs	7.8	1.6	MHA	75.9	22.4	28.4	20	2.6	4.8	492	F ascorbate	11.6	0.8	NBP	92.4	32.1	34.6	88	144	36	308	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
43	10003605	Aiza	F	14 months	10.2	1.6	MHA	72.4	24.6	28.4	26	4	14	410	F ascorbate	12.8	0.8	NBP	98	32.4	36	142	270	36	302	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
44	10003529	Poorvi	F	5 yrs	10	1.6	MHA	66.4	24.8	29.4	32	9.8	12	396	F ascorbate	12.4	0.8	NBP	89.2	30.4	34.8	56	108	34	321	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
45	10003350	Yusuf	M	16 months	9.3	0.9	MHA	66.4	16.8	29.4	14	12.2	4	462	F ascorbate	11.8	0.6	NBP	88.8	30.2	34.6	64	50.2	38	328	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
46	10003424	Bhagyashree	F	17 yrs	8.6	1.8	MHA	68	20	29.2	18	6.8	6	426	F ascorbate	12.6	0.9	NBP	92.4	32.6	34.8	68.4	78	36	302	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
47	1188421	Bhushan	M	13 yes	10.9	0.9	MHA	62	19.1	30.8	63	25.8	18	342	F sulfate	11.6	1.2	NBP	90.6	32	34.6	54	30.6	31	296	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
48	1188959	Mariyam	F	13 months	8.3	0.6	MHA	76.2	21	28.2	30	9	14	340	F sulfate	12.4	0.6	NBP	86.5	29.4	36.2	68	18	36	310	NO	NO	NO	2 Days	NO	10 Days	NO	NO	NO	NO
49	1186695	Satish	M	14months	8.9	1	MHA	70	21.6	29.7	17	6.8	4	442	F sulfate	11.2	1.4	NBP	90	28.6	34	54	106	36	326	NO	NO	NO	NO	NO	NO	NO	NO	2 Days	NO
50	1189222	Md Harish	M	6 yrs	9.8	0.7	MHA	60.4	18.3	30.2	12	5	4	496	F sulfate	11.2	0.6	NBP	88.6	29.8	34.6	85	186	34	310	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
51	1189930	Atarava	M	5 yrs	10.1	1.7	MHA	76.6	24.2	31.7	14	5.6	6	406	F sulfate	12.4	0.8	NBP	90	30.1	34.6	64	96.4	36	326	NO	YES	NO	NO	1 day	NO	NO	NO	NO	NO
52	1193793	Mallikarjun	M	20 months	6.6	1.2	MHA	68.2	26.8	29.4	25	33.7	5	510	F sulfate	10.4	0.6	NBP	87.6	29	32	58	62	34	348	2 days	NO	NO	NO	NO	NO	NO	NO	NO	NO
53	1198656	Shreesail	M	9 yrs	9.3	0.9	MHA	68.9	22.6	29	36	9.4	16	358	F sulfate	12.4	0.7	NBP	88.6	32	34.8	106	158	36	310	NO	NO	NO	NO	NO	2 days	NO	NO	NO	NO
54	1199163	Divya	F	16 yrs	7.9	0.9	MHA	56.4	21	26.4	34	75.9	11	310	F sulfate	11.8	1	NBP	86.4	31	35.8	74	108	40	308	NO	NO	NO	3 days	NO	NO	NO	NO	NO	NO
55	1196791	Charan	M	5 yrs	10.6	0.7	MHA	67.3	22.8	26	30.8	10.6	16	358	F sulfate	11.7	0.6	NBP	82.5	26.9	31.4	68	76	34	310	2 days	NO	NO	NO	NO	NO	NO	1 day	NO	NO
56	1199246	Nawaj	M	10 yrs	10.8	2.1	MHA	73.2	23.9	29	36	8	12	368	F sulfate	12.9	1	NBP	98	29	34.6	72	116	34	308	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
57	1198381	Ishan	M	5 yrs	10.5	0.9	MHA	71.5	22.2	27.4	32	8	9	328	F sulfate	12.6	1.2	NBP	88.1	26	32.4	98	29.4	31	306	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
58	1197113	Aadhya	F	3 yrs	9.3	0.8	MHA	66.2	24.8	26.9	16	10.6	3	408	F sulfate	12.6	0.7	NBP	85.5	26.6	31.1	48	196	34	305	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
59	1199093	Yallappa	M	10 yrs	11	0.7	MHA	75	23.7	31.6	57	20.6	14	338	F sulfate	13.4	0.9	NBP	90.2	30.6	35.4	108	226.4	36	301	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
60	1201083	Siddappa	M	17 yrs	10.6	0.6	MHA	74.9	23.6	31.6	13	5	3	486	F sulfate	13.6	0.9	NBP	88.6	29	34.6	148	266	34	298	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
61	1202295	Amruta	F	8 yrs	10.2	0.9	MHA	71.4	20.5	26.4	28	9.2	14	368	F sulfate	11.9	0.8	NBP	88.9	28	32.4	44	86	34	301	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
62	1202253	Rafiya	F	4 yrs	9.8	1.6	MHA	62.8	20.6	28.4	13	4.8	14	360	F sulfate	12.4	1.5	NBP	88.6	28.4	31.6	64	72.6	34	302	10 Days	NO	NO	NO	NO	NO	YES	NO	NO	NO
63	1200571	Vinod	M	4 yrs	10.4	1	MHA	71.9	21.5	29.1	13	9	4	406	F sulfate	12.4	0.9	NBP	84.6	28.4	32.8	148	76	34	316	NO	NO	YES	NO	NO	NO	NO	NO	NO	NO
64	1202237	Humaid	M	4 yrs	10.7	0.6	MHA	62.8	18.6	27	14	10	3	438	F sulfate	12.6	0.9	NBP	89	28.6	32.4	85	126	34	301	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
65	1200718	Bhoomika	F	4 yrs	10.5	1.3	MHA	71	26	28.6	62	20.6	28	436	F sulfate	12.4	1.8	NBP	88.6	31	36	86	104	34	301	NO	NO	NO	NO	NO	NO	NO	NO	NO	1 day
66	1201157	Ishankhan	M	11 yrs	7	2.5	MHA	61.2	20.6	22.4	31	20.6	3	512	F sulfate	11.4	0.9	NBP	90.6	29.8	34.6	96	88.6	36	401	NO	NO	NO	NO	NO	1 day	NO	NO	NO	NO
67	1202089	Irfa	F	8 yrs	10.6	1.3	MHA	71	26	28.6	64	22.6	29.4	386	F sulfate	12.4	1.6	NBP	92	32	34.6	68	114	38.6	301	NO	NO	NO	3 days	NO	NO	NO	NO	NO	NO
68	1201167	Mayeez	M	15 yrs	8.2	1.4	MHA	65.1	16.1	25.5	15	25.8	4	401	F sulfate	11.6	1.2	NBP	90	29.4	32.4	145	46	40	306	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
69	1202381	Ananya	F	8 yrs	10.6	0.9	MHA	62.8	21.6	27	16	10	3	440	F sulfate	13	0.9	NBP	90.2	29.6	32.6	64	58.6	34	308	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
70	1201564	Basavaraj	M	13 yrs	9.7	1.3	MHA	76	24	28	13	9.6	4	308	F sulfate	11.8	1.6	NBP	88.6	30.8	34	68	46.4	34	316	NO	NO	NO	NO	NO	NO	NO	NO	2 Days	NO
71	1201692	Shrushti	F	12 yrs	10.6	0.9	MHA	71.2	20.5	28.7	29	6	8	306	F sulfate	13.6	1.4	NBP	90.4	30.4	34.6	56	142	34	301	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
72	1202411	Manasi	F	7 yrs	10.2	0.9	MHA	70.6	21.4	28	30	9	14	354	F sulfate	12.6	1.2	NBP	90.4	28.6	32.4	58	110.2	34	301	NO	NO	NO	NO	1 day	NO	NO	NO	NO	NO
73	1202419	Zaid	M	11 yrs	9.1	0.8	MHA	70	21.4	26.8	54	10.6	14	359	F sulfate	11.8	0.9	NBP	90.4	30.6	34	54	116	38	301	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
74	1197095	Harsha	M	15 yrs	9.7	0.8	MHA	70.9	20.6	30.4	12	5	4	496	F sulfate	12.4	1	NBP	90.2	29.6	31.2	64	76.4	36.4	314	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
75	1204233	Ajay	M	4 yrs	10.5	0.8	MHA	71	21.6	29.4	14	5.6	6	406	F sulfate	13	1.2	NBP	89.4	30.4	34.6	64	108	36	316	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
76	1203706	Sakshi	F	10 yrs	10.2	0.9	MHA	68.9	22.6	29	36	9.4	16	258	F sulfate	12.6	0.8	NBP	88.6	30.4	34.6	54	108	36	321	NO	NO	NO	NO	NO	2 days	NO	NO	NO	NO
77	1203716	Sunil	M	14 yrs	10	0.8	MHA	59.3	18.5	31.2	36	8.4	10	398	F sulfate	12.8	0.6	NBP	88.6	30.2	34.6	148	56	34	301	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO

78	1204126	Amogh	M	3 yrs	10.6	0.8	MHA	71	20.4	26	30.8	10.6	16	358	F sulfate	11.8	1.4	NBP	90.2	28.6	34.2	58	108	34	316	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO
79	1204237	Veeresh	M	8 yrs	10.5	0.9	MHA	70.2	22.4	28.1	16	10.8	6	388	F sulfate	12	0.8	NBP	88.4	30.6	34.2	70	38	34	316	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO
80	1203701	Birappa	M	5 yrs	10.6	0.8	MHA	69.7	21.5	30.9	16	10	3	408	F sulfate	12.8	0.6	NBP	88.8	30.2	34.2	60	68	38	304	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
81	1203703	Hulas	M	5 yrs	10.6	0.8	MHA	69	21	30.2	57	20.6	14	338	F sulfate	12.9	1	NBP	89.5	31.5	35.2	88	74.8	36	316	NO	NO	NO	NO	NO	2 days	NO	NO	NO	NO
82	1204221	Thanushree	F	6 yrs	10.5	1.6	MHA	78.3	21.2	28.8	18	29.1	6	398	F sulfate	13.4	0.7	NBP	88.6	32	34.8	106	158	36	310	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO
83	1204351	Adwait	M	3 yrs	7.8	2.5	MHA	61.2	20.6	26.4	31	20.6	3	512	F sulfate	11.7	0.6	NBP	88.5	27	32.4	72	78	36	308	NO	NO	NO	3 days	NO	NO	NO	NO	NO	NO
84	1206022	Amar	M	14 months	9.8	1.3	MHA	62.8	18.5	29.5	26	4	6.6	400	F sulfate	11.2	0.8	NBP	86.8	28.6	32.6	39	106	36	310	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
85	1207201	Kartik	M	1.5 yrs	10.8	0.7	MHA	72.8	22.9	31.4	36	4	7	396	F sulfate	12.6	0.7	NBP	86.8	28.4	34.6	50	106	36	302	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
86	1208958	Shravani	F	2 yrs	9.6	3.1	MHA	66.2	14.7	26.2	32	3.9	7.2	464	F sulfate	14.8	1.6	NBP	94.6	32.8	36.4	108	236	37	298	NO	NO	NO	NO	NO	3 days	NO	NO	NO	NO
87	10000513	Sana	F	2.5 yrs	10.3	1.8	MHA	64.8	18.2	26.1	30	7.6	7.2	406	F sulfate	12.6	0.6	NBP	90.2	30.6	32.8	58	68.6	34	306	NO	NO	NO	NO	2 days	NO	NO	NO	NO	NO
88	10004216	Shiva singh	M	3 yrs	8	1.4	MHA	68.5	20.3	29.6	34	4	7	498	F sulfate	11.8	0.9	NBP	90.6	29	33.8	84	126	38	310	1 day	NO	NO	NO	NO	NO	NO	NO	NO	NO
89	10000150	Aiza	F	2 yrs	10.6	1.8	MHA	70.1	21.2	30.2	19	14.5	5	360	F sulfate	12	1	NBP	89.6	29.4	34.8	78	156	38	314	NO	NO	NO	NO	1 day	NO	NO	NO	NO	NO
90	10000759	Samarth	M	6 yrs	10.2	0.9	MHA	68.4	20.6	30.2	70	7.8	5	396	F sulfate	12	1.6	NBP	98	32	36	78	112	38	302	NO	NO	NO	4 days	NO	NO	NO	NO	NO	NO
91	1209444	Shivanand	M	9 yrs	10.9	0.8	MHA	60.4	18.6	30.2	38	12.4	10	398	F sulfate	12.6	0.9	NBP	90.2	32.4	34.6	138	152	33	316	NO	NO	NO	NO	NO	NO	YES	NO	NO	NO
92	10000644	Aliya	F	11 yrs	9.4	2	MHA	66.8	22.4	30.2	28	4.2	10	432	F sulfate	12	0.8	NBP	96.4	28.2	34.2	108	152	38	312	NO	YES	NO	NO	NO	2 days	YES	NO	NO	NO
93	10001151	Jyoti	F	14 yrs	10.2	1.9	MHA	69.8	20.6	28.4	64	9	4	398	F sulfate	11.8	0.8	NBP	88.8	29.4	35.6	97.6	48	26	328	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO
94	10000697	B/O Channamma	M	14 months	8.6	1.7	MHA	70.2	20.4	28.8	28	76.6	7	424	F sulfate	11.2	0.8	NBP	90	28.8	35.2	68	220	38	321	NO	NO	NO	NO	1 day	NO	NO	NO	NO	NO
95	10003057	Ragini	F	11 yrs	9.4	1.9	MHA	69.4	20.6	30.2	18	11.4	4	446	F sulfate	11.8	0.6	NBP	90.8	32.2	35.6	52	164	38	334	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
96	10002957	Satyappa	M	3 yrs	7.9	1.4	MHA	62.8	20	28.4	12	18.6	4	459	F sulfate	11.8	0.6	NBP	90.6	30	33.8	88	144	38	316	NO	YES	NO	NO	NO	NO	YES	NO	NO	NO
97	10003326	Bhavana	F	6 yrs	8.8	2.2	MHA	68.6	20.8	28.8	36	4.6	7	496	F sulfate	11.4	1	NBP	90.2	28.9	34.2	88.6	130.2	36	314	NO	NO	NO	NO	NO	4 days	NO	NO	NO	NO
98	10002015	Danesh	M	16 yrs	9.8	1.6	MHA	60.4	18.6	32	38	8.6	10	398	F sulfate	12.2	0.6	NBP	92.4	30.2	34.6	146	45	32	308	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO