SYSTEMATIC REVIEW

Iron Preparations in the Management of Iron Deficiency Anemia in Infants and Children: A Systematic Review and Meta-Analysis

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Background: Various therapeutic iron preparations are available in the market, which differ in their pharmacokinetic and safety profiles. There is insufficient evidence regarding the superior safety or efficacy of one over the other.

Objectives: To study the effects of iron preparations on various parameters like hemoglobin, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH) and serum ferritin.

Study design: A systematic review and meta-analysis of randomized controlled trials (RCT) was conducted from inception till 3 June, 2022.

Data sources and selection criteria: Databases like MEDLINE and COCHRANE were searched for RCTs evaluating the effects and safety profile of various iron salts in the management of iron deficiency anemia in children and adolescents.

Main results: Eight studies with a total of 495 children were included the review. Pooled analysis showed ferrous sulphate to cause a significant increase in hemoglobin compared with other iron compounds [mean difference (95% CI) 0.53 (0.22 to 0.83; *P* <0.001]. Also ferrous sulphate is superior to iron polymaltose complex (IPC) (*P*<0.001). However, there was a significant increase in gastrointestinal adverse effects with ferrous sulphate compared to IPC (*P*=0.03). Other iron compounds were more efficacious than IPC in raising hemoglobin levels (*P*<0.001). Among the few studies evaluating iron indices like MCV, MCH, and serum ferritin, there was no significant difference between the iron preparations (*P*>0.05). **Conclusions**: A low quality evidence suggests that ferrous sulphate is more efficacious than other compounds (*P*<0.001); though, there is an increase in gastrointestinal side effects with ferrous sulphate.

Key words: *Ferrous sulphate, Iron polymaltose complex, Hemoglobin*.

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Nutritional deficiency of iron is common in the population because most naturally occurring iron is in Ferric form which is poorly absorbed from the diet [1]. As per World Health Organization (WHO) estimates, the global prevalence of anemia in children aged 6-59 months is 39.8% in the year 2019 [2], and according to the National Family Health Survey 5, the prevalence of anemia in India during the year 2019 was 53.4% [3].

Iron is not only important for hemoglobin synthesis but also for a variety of enzyme systems. Therefore iron deficiency produces anemia as well as other symptoms like organ and tissue dysfunction, impaired immunity, fatigability, decreased cognitive capabilities and poor weight gain [1,4].

Iron supplementation is one of the key strategies for the treatment of iron deficiency anemia (IDA). Most iron salts used for treatment of iron deficiency exist in ferrous form which is easily bioavailable. After supplementation, it takes around 24 hours to replace intracellular enzymes, followed by increase in hemoglobin over a month. Replenishing of iron stores takes one to three month time [5]. Various iron salt preparations are available including ferrous sulphate, iron polymaltose complex (IPC), iron bisglycinate chelate, ferrous ascorbate, colloidal iron, iron-zinc and lactoferrin 100. There is insufficient evidence regarding the superior safety or efficacy of one over the other.

This systematic review was undertaken with the objective of comparing various iron compounds with ferrous sulphate and IPC, and to correlate with hematologic indices including hemoglobin, means corpuscular hemoglobin (MCH), mean corpuscular volume (MCV) and serum ferritin.

METHODS

This systematic review and meta-analysis was conducted and is being reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [6]. The protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database prior to commencement of the study.

Search eligibility: Randomized controlled trials from inception till 3 June, 2022, comparing the efficacy of different iron preparations in children aged between 6 months and 15 years of age, diagnosed to have IDA, based on hemoglobin values, were included in the review. The primary outcome measure was the effect on hemoglobin, and secondary outcomes include serum ferritin, changes in hemoglobin, MCV, MCH and gastrointestinal adverse effects.

Search strategy: The authors independently conducted searches of medical databases namely MEDLINE and COCHRANE center register of controlled trials published in English language. The electronic search strategy included a combination of keywords along with their representative Medical Subject Headings (MeSH). The details of search strategy are provided as **Web Box 1**.

Data extraction: Two authors independently searched the data using a pre-designed form. Disagreement, if any, was resolved by a third author. Details of study including author, place and year of study and characteristics of infants were included.

Quality assessment: Quality of studies was assessed independently by authors for each study using the risk of bias (RoB) criteria outlined in the Cochrane handbook for systematic review of intervention in the domains of random sequence generation, allocation concealment, blinding of participant and personnel, blinding of outcome assessment, incomplete outcome data, and selective reporting of results.

Statistical analysis: Statistical analysis was done using Review Manager version 5.4 (The Cochrane Collaboration, 2020). Outcome variables were noted as mean differences with 95% CI for continuous data. For dichotomous data, outcome variables were noted as risk ratio (RR) with 95% CI. When hemoglobin and other iron parameters were measured at different time points after starting therapy, those values obtained at the longest follow-up of each study were included in the analysis. Results were pooled using either fixed or random effects model based on heterogeneity. Between studies heterogeneity was assessed with a chi-square test and the I^2 statistic. A P value of <0.1 for the chi-square statistic indicated significant heterogeneity. Sensitivity analysis was done after excluding other studies comparing ferrous sulphate with other iron preparations excepting IPC, which revealed no heterogeneity after exclusion. Quality of evidence was assessed by Grading of recommendations, Development and Evaluation (GRADE) approach [7] to assess the quality of evidence using GRADE pro GDT tool.

RESULTS

Using the search strategies mentioned, 1878 records from two databases COCHRANE and MEDLINE were identified and screened for eligibility. Of these, 15 studies were found to be eligible, but after exclusions, eight studies with a total of 495 children were included in the review (**Fig. 1**). The age group of children ranged from 6 months to 17 years. The dosage of iron used ranged from 3 mg/kg/day to 6 mg/kg/day. Ferrous sulphate was compared with IPC in four of the studies. The other comparisons included iron bisglycinate chelate and IPC, ferrous sulphate and iron bisglycinate chelate, ferrous ascorbate and colloidal iron, and IPC and ferrous ascorbate. Rise in hemoglobin was the final outcome evaluated in all the studies, whereas serum ferritin, MCV, MCH and hematocrit were the secondary outcomes evaluated. The duration of iron therapy ranged from 28 days to 3 months. Adverse effects were evaluated in three studies [8-10] (**Table I**).

Two of the studies [10,11] had high risk of bias due to improper randomization (**Fig 2** and **3**). In one study [10], randomization was altered on a weekly basis, whereas in the other study [11], children were randomized to treatment groups in a consecutive fashion. Pineda, et al. [12] had some concerns due to improper randomization and deviation from intended interventions. Other five studies had low risk of bias. Though blinding of participants and people delivering interventions was done in only two studies [9,13], all the included studies had low risk of performance bias. Also, an appropriate analysis (Intention to treat analysis) was used in all the studies. In summary, 25% of studies had high risk of bias, whereas 12.5% had some concerns of risk of bias.

Outcome data were available for nearly all participants in five studies [8,10,12-14]. Though there was significant loss to follow-up at the end of the treatment period in three studies [9,11,15], the result was not biased by the missing outcome data and the loss to follow-up could not be attributed to

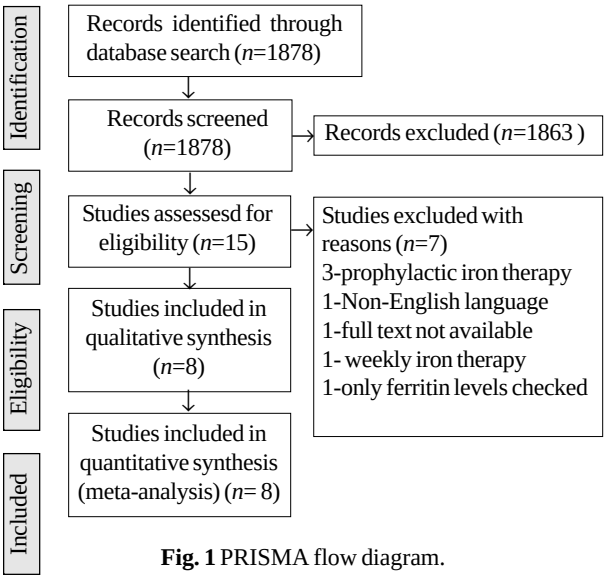

Fig. 1 PRISMA flow diagram.

Table I Characteristics of Included Studies

Author, country, year	*Participants (N; age)*	*Dose of iron (mg/kg/d)*	*Duration of treatment*	*Interventions (n)*	*Outcomes assessed*	*Study findings*
Powers, USA, 2013-2016 [9]	59 9-48 mo	3	12 wk	Ferrous sulphate (28), Iron polysaccharide (31)	Hb, Ferritin, TIBC, Adverse effects	E[a]: FeS[c] >IPC (P<0.001) SE[b]: IPC >FeS (P=0.62)
Name, Brazil, 2016 [13]	20; 1-13 y	3	45 d	Iron bisglycinate Chelate (FeBC), Polymaltose iron	Hb, Ferritin, Transferrin, MCV, MCH, RDW	E: IPC[d] = FeBC (P =1)
Yasa, Turkey, 2009 [10]	103; 7 mo 17 y	5	4 mo	IPC (52), Ferrous sulphate (51)	Hb, Ferritin, Serum Fe, TIBC, Transferrin saturation, MCV, MCH, MCHC, RBC count, Hct, Adverse effects	E: FeS >IPC (<0.001) SE: FeS >IPC (P=0.012)
Patil, India, 2016-2017 [15]	100; 1-12 y	6	3 mo	IPC (50), Ferrous ascorbate (50)	Hb, MCV, RDW, Reticulocyte count	E: FA[e] >IPC(P<0.001)
Pineda, Guatemala, 2001 [12]	40; 6-36 mo	5	28 d	Ferrous sulphate (20), Ferrous bisglycinate chelate (20)	Hb, Ferritin	E: FeS=FEBC (P=1)
Yewale, India, 2008 [14]	66; 6 mo - 12 y	3	12 wk	Ferrous ascorbate (37), Colloidal iron (29)	Hb, Hct, MCV, MCH, MCHC	E: FA >C.iron[f] (P<0.001)
Bopche, India, 2004 - 2005 [8]	106; 1-6 y	6	1 mo	IPC (53), Ferrous sulphate (53)	Hb, side effects	E: FeS >IPC (P<0.001) SE: FeS=IPC (P=0.14)
Ozsurekci, Turkey, 2008-2009 [11]	60; 6 mo - 15 y	6	8 wk	ferrous sulphate, Polymaltose complex, Iron-zinc	Hb, reticulocyte count	E: FeS=IPC (P=0.068)

[a]Efficacy defined by significant increase in hemoglobin (P< 0.05); [b]gastrointestinal side effects. [c]FeS: ferrous sulphate; IPC: iron polymaltose 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.

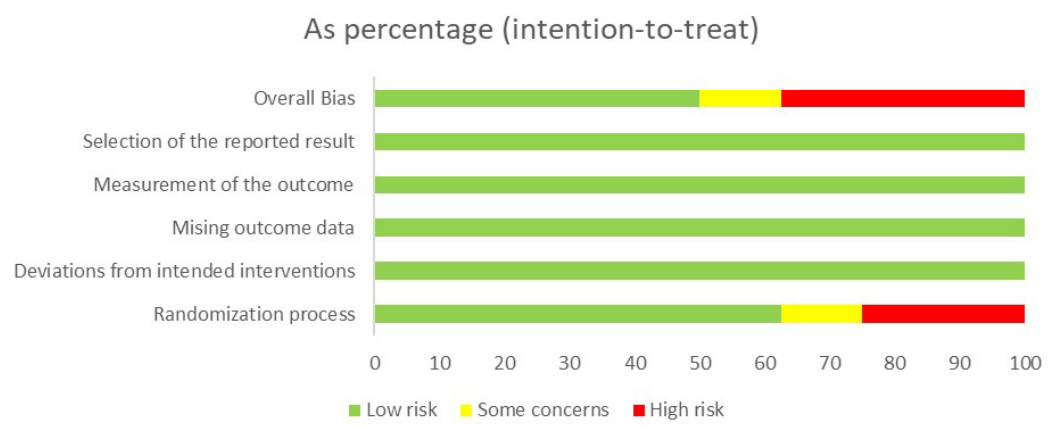

Fig.2 Risk of bias in the included studies.

Fig. 3 Risk of bias summary for included studies, showing authors' judgements about each risk of bias item for each included study.

decreased efficacy or significant side effects of the interventions. None of the studies had bias due to selective reporting.

The pooled effect size of the five studies [8-12] comparing ferrous sulphate with other iron compounds showed that ferrous sulphate caused a statistically significant increase in the mean hemoglobin when compared to other iron compounds [mean difference (95% CI) 0.53 (0.22-0.83); *P*<0.001] (**Fig.4**). The pooled effect sizes of the six studies [8-11,13,15] comparing IPC with other iron compound showed that other iron compounds cause a significant increase in hemoglobin compared with IPC [MD (95% CI) -0.70 (-0.99 to -0.41); *P*<0.001] (**Fig.4**). Sensitivity analysis was done due to difference in comparators. In four studies [8-11] comparing ferrous sulphate with IPC, ferrous sulphate caused a statistically significant increase in hemoglobin compared to other IPC [MD (95% CI) 0.68 (0.5-0.86); *P*<0.001]. In two studies comparing ferrous ascorbate with other iron compounds, ferrous ascorbate caused a significant increase in hemoglobin compared with other iron compounds [MD (95% CI) 1.45 (1.00-1.91); *P*<0.001].

Regarding the outcome of change in hemoglobin from baseline, three studies [10,12,15] evaluated this outcome. In two of these studies [10,12] comparing ferrous sulphate with other iron compounds, the change in hemoglobin was not statistically significant [MD (95% CI) 0.15 (-0.41 to 0.72); *P*=0.60]. In studies [10,15] comparing IPC with other iron compounds, there was a statistically significant change in hemoglobin in the other iron compound group [MD (95% CI) -1.27 (-1.68 to -0.85); *P*<0.001].

In two studies evaluating MCH [10,13], comparison of IPC with other iron compounds showed no significant difference [MD (95% CI) 0.11 (-0.43 to 0.65); *P*=0.68]. With regard to MCV, two studies [10,13] comparing IPC with other iron compounds, there was no significant change in MCV [MD (95% CI) -0.05 (-1.37 to 1.28); *P*=0.94]. Data on serum ferritin was obtained in four studies [9,10,12,13] including 222 children. In two studies [12,13] comparing iron bisglycinate chelate with other iron compounds, the change in ferritin levels were not statistically significant [MD (95% CI) 3.47 (-0.51 to 7.45); *P*=0.09].

Gastrointestinal side effects were significantly more in ferrous sulphate [OR (95% CI) 1.86 (1.06 to 3.26); *P*=0.03) compared with IPC [8-10] (**Fig.4**).

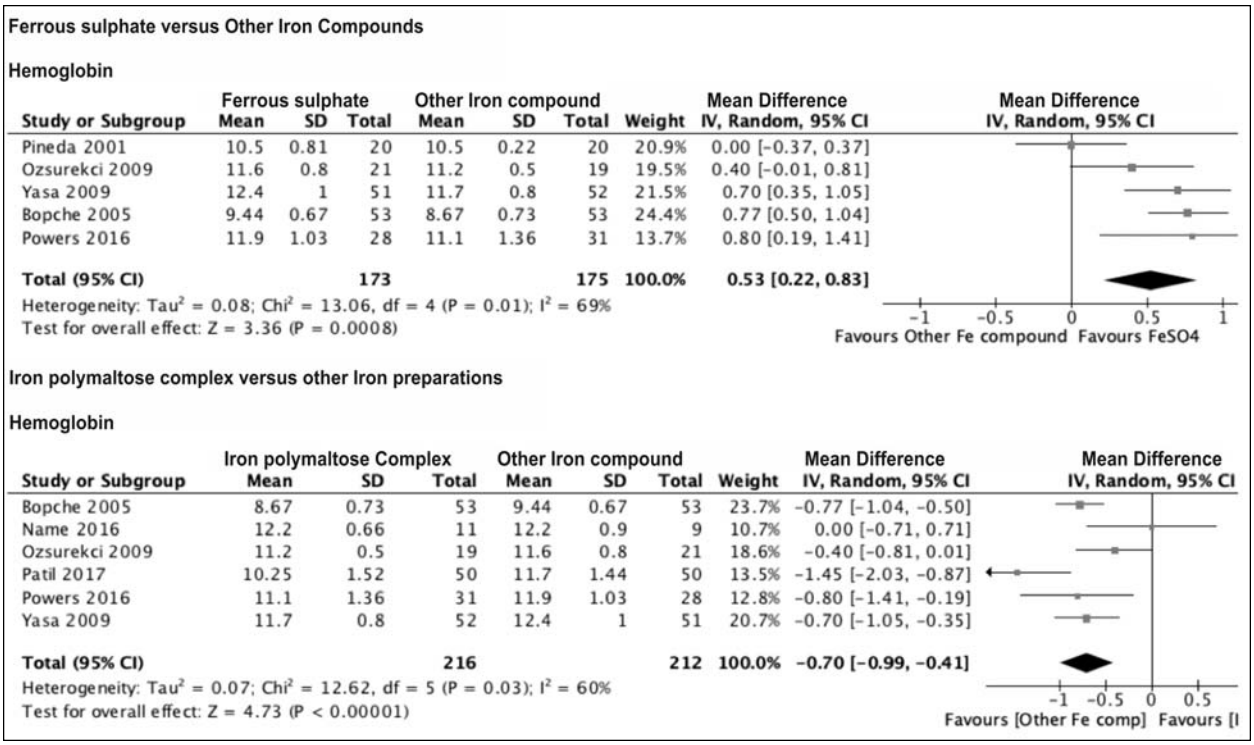

Fig. 4 Effect on hemoglobin levels of ferrous sulphate and iron polymaltose complex preparations vs other iron compounds for iron deficiency anemia in infants and children.

DISCUSSION

In the present review, a low quality of evidence suggests that ferrous sulphate causes a significant increase in hemoglobin when compared to other iron compounds. Also, a moderate quality of evidence showed that other iron compounds are better than IPC. Gastrointestinal side effects are slightly more with ferrous sulphate than IPC.

There are several limitations regarding the comparability of studies included in the review. The dosage of iron used in these studies ranged from 3-6 mg/kg/day. The duration of therapy ranged from 28 days to 3 months. The age group ranged from 6 months to 17 years. Blinding was done only in three studies [9,12,13]. The quality of evidence was low regarding hemoglobin levels in trials comparing ferrous sulphate with other iron compounds. While hemoglobin levels were reported in all studies, other outcomes like MCV, MCH, change in hemoglobin and serum ferritin were reported in only some of the studies.

In an earlier review done by Gera, et al. [16], it was found that iron supplementation modestly improves iron deficiency anemia in children. In most of the studies included in this review, different iron formulations were compared with placebo. In a review done by Rosli, et al. [17], it was shown that ferrous sulphate was superior to IPC. Also there was no significant difference in the side effects between the two

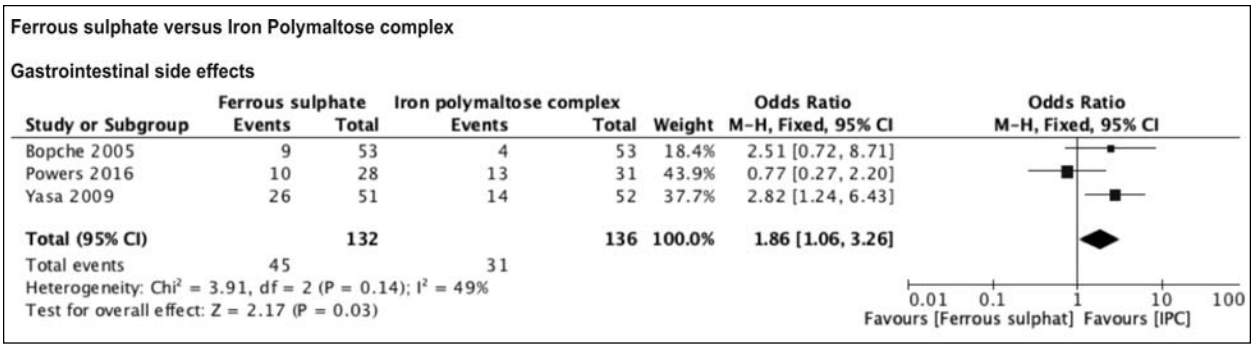

Fig 5. Gastrointestinal side effects of ferrous sulphate vs iron polymaltose computer for iron deficiency anemia in infants and children.

preparations. In an iron supplementation trial in preterm and low birth weight infants [18], it was found that there were no beneficial effects in the short term, but resulted in an improvement in iron status and iron deficiency. In another meta-analysis done by Low, et al. [19], it was found that iron supplementation safely improves hematologic and non-hematologic parameters in primary school aged children in low- and middle-income countries. It was also found that ferrous sulphate, when compared to placebo, improves global cognitive performance.

In an overview of reviews done by Mithra, et al. [20], it was found that in pre-school children, iron with multiple micronutrients (MMN) fortification significantly reduced the risk of anemia (by 55%), whereas, in school-aged children (under 12 years of age), the same showed better response (84% reduction in risk of anemia). In two reviews [21,22], it was found that in infants, home fortification (adding packets containing multiple micronutrients i.e., vitamins and minerals including iron with complementary foods of children) was better than iron supplementation in prevention of anemia. However, in anemic infants, medical iron drops is better than home fortification alone. In older children and adolescents (3.5 to 18 years), daily iron with or without multivitamins is better than intermittent iron [23,24]. However, these reviews did not compare different iron formulations in the management of anemia.

A review of anemic children in malaria endemic areas [25] compared iron with placebo or other supplemental nutrients like multivitamins, vitamin A, zinc, albendazole or mebendazole. The review included many outcome measures like clinical malaria, all-cause mortality, hospitalizations, weight, anemia, including hemoglobin at the end of treatment and change in hemoglobin with treatment. The pooled analysis of 13 trials in the review found that iron supplements (commonly ferrous sulphate) significantly improved hemo-globin compared with placebo. Importantly, all these studies, except one [26], did not compare different iron preparations, which was a prerequisite for our review and meta-analysis. Of these, Zlotkin, et al. [27] was the only study which had four treatment arms, of which two were different iron preparations i.e., microencapsulated iron fumarate and ferrous sulphate drops. But it was given as a supplement to non-anemic children (presence of anemia defined by hemoglobin levels is a prerequisite in our review). In fact, placebo group showed better response than ferrous sulphate drops in these non-anemic children in the study. In other studies, treatment arms included iron along with other supplements like zinc [27], vitamin A [28], antihelminthic agents [29,30], or multivitamins, micronutrients [31,32]. In all of these studies, placebo was one of the treatment groups. Hence these studies were not included in our meta- analysis.

In summary, a low quality of evidence suggests that ferrous sulphate is superior to other iron compounds in the management of iron deficiency anemia in young infants, children and adolescents. Moderate quality of evidence on adverse effects suggests that there is slightly more adverse effects with ferrous sulphate compared to IPC. Further research is needed to investigate the efficacy and safety of other less known compounds like ferrous gluconate, ferrous fumarate, etc.

Contributors: CSA: conceptualized the review, literature search, data analysis and manuscript writing; ABT: literature search, data analysis and manuscript writing; SM: conceptualized the review, literature search, data analysis and manuscript writing.
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Note: Additional material related to this study is available with the online version at *www.indianpediatrics.net*

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Web Box I Details of the search strategy

MEDLINE

("Oral iron preparation" or iron supplements* or ferrous ascor-bate* or ferrous gluconate* or colloidal iron* or ferrous fuma-rate* or ferrous sulphate* or ferrous sulfate* or iron salt* or Carbonyl iron* or iron polysaccharide complex* or iron poly-maltose complex* or Iron Protein Succinylate* or ferri manni-tol ovalbumin* or iron bisglycinate* or ferrous bisglycinate* or ferrous glycine sulfate* or ferrous glycine sulphate* or ferric pyrophosphate* or sucrosomal Iron* or ferrous compounds* or ferric compounds* or lactoferrin*) and ((("iron deficiency ane-mia" or nutritional anemia* or microcytic hypochromic ane-mia*))) and (("children" or infants* or child*))

CENTRAL

Search words: Iron preparations for iron deficiency anemia in children

ID Search

#1 iron deficiency in Trials (Word variations have been searched)

#2 MeSH descriptor: [Anemia, Iron-Deficiency] explode all trees

#3 #1 or #2

#4 iron compound in Trials

#5 iron preparation in Trials

#6 MeSH descriptor: [Iron Compounds] explode all trees

#7 ferrous

#8 ferric

#9 #4 or #5 or #6 or #7 or #8

#10 infant

#11 children

#12 #10 or #11

#13 #3 and #9 and #12