Study Eligibility & Data Collection Form

General Information

Study ID *(e.g. author name, year)*	Bopche, 2009
Form completed by	Ritzzaleena Rosli Mohd Rosli
Study author contact details	ritzz.rosli@student.usm.my
Publication type *(e.g. full report, abstract, letter)*	Full report
List of included publications	-
References of similar trial*	-

*This is when the authors published the same study in several reports. All these references to a similar trial should be linked under one *Study ID* in RevMan.

Study eligibility

	Yes	No	Unclear	Further details
RCT/Quasi/CCT	**/**			RCT
Relevant participants	**/**			
Relevant interventions	**/**			
Relevant outcomes*	**/**			

*Include only if the presence of outcomes form the inclusion criterion

If the above answers are 'YES', proceed to Section 1.

If any of the above answers are 'NO*', record below the information for 'Excluded studies'

Reason(s) for exclusion
-

Section 1. Characteristics of included studies

This section is to be completed by only one reviewer. State initials: RRMR

METHODS	**Descriptions as stated in paper**
Aim of study *(e.g. efficacy, equivalence, pragmatic)*	To determines the therapeutic efficacy of two different oral iron preparations: iron polymaltose complex (IPC) and ferrous sulfate (FS).
Design *(e.g. parallel, crossover, cluster)*	Parallel study comparing Iron Polymaltose and Ferrous Sulphate
Unit of allocation *(by individuals, cluster/ groups or body parts)*	individuals
Start & end dates	October 2004 – September 2005
Total study duration	1 year
Sources of funding *(including role of funders)*	None
Possible conflicts of interest *(for study authors)*	Not stated

PARTICIPANTS	**Description** *(include information for each intervention or comparison group)*
Population description *(Company/companies; occupation)*	Children with Iron deficiency anaemia
Setting *(including location (city, state, country) and single centre / multicenter)*	Teaching institution with a tertiary level paediatric centre in central India.
Inclusion criteria	1. Age ranging from 1-6 years 2. IDA confirmed by serum iron chemistry
Exclusion criteria	Not mentioned
Method of recruitment of participants *(e.g. phone, mail, clinic patients, voluntary)*	Patients attending outpatient department
Total no. randomised	118
Clusters *(if applicable, no., type, no. people per cluster)*	No

No. randomised per group *(specify whether no. people or clusters)*	Intervention: 59 Control: 59
No. missing *(if overall, e.g. exclusions & withdrawals, whether or not missing from analysis)*	Intervention: 6 Control:6
Reasons missing	Lost to follow up
Baseline imbalances	No
Age	1-6 years old
Sex (proportion)	Not mentioned
Race/Ethnicity	Indian
Other relevant sociodemographic	-
Subgroups measured *(e.g. split by age or sex)*	-
Subgroups reported	-

Section 2. Risk of bias assessment

We recommend you refer to and use the method described in the Cochrane Handbook.

This section is completed by two reviewers. State initials: (i) RRMR (ii) NMN

Domain	**Risk of bias**			**Support for judgement** *(include direct quotes where available with explanatory comments)*	**Location in text or source** *(page, table)*
	Low	High	Unclear		
Random sequence generation *(selection bias)*	Low			*"Randomization was achieved by simple randomization"*	Page 2
Allocation concealment *(selection bias)*	Low			*"and allocation was concealed by sealed envelope technique."*	Page 2
Blinding of participants and personnel *(performance bias)*	Unclear			Not mentioned in full text	-
Blinding of outcome assessment *(detection bias)*	Low			Outcome is base on laboratory results from blood sample. Comment: Objective / continuous outcome	Page 2
Incomplete outcome data *(attrition bias)*	Low			Number of missing participants are equal in each group and both for similar reason.	Figure 1: study flow chart, page 2
Selective outcome reporting *(reporting bias)*	Low			Study protocol not available All pre-specified and expected outcomes of interest are reported	-
Other bias	Low			No other bias identified	-

Random sequence generation = Process used to assign people into intervention and control groups
Allocation concealment = Process used to prevent foreknowledge of group assignment in a RCT
Blinding of participants and personnel = Presence or absence of blinding for participants and health personnel
Blinding of outcome assessment = presence or absence of blinding for assessment of outcome
Incomplete outcome data = application of intention-to-treat analysis is one in which all the participants in a trial are analysed according to the intervention to which they were allocated
Selective outcome reporting = Selection of a subset of the original variables recorded

Section 3. Intervention groups

This section is completed by two reviewers. State initials: (i) RRMR (ii) NMN

Outcomes relevant to your review *(Copy and paste from 'Types of outcome measures')*	**Reported in paper** *(Yes / No)*	**Outcome definition** *(with diagnostic criteria if relevant)*	**Unit of measurement & tool** *(if relevant)*	**Reanalysis required?** *(specify)*
1. Haemoglobin (Hb)	Yes	level at end of treatment	(g/dL)	No
2. Serum Ferritin	No	-	-	No
3. Serum iron	No	-	-	No
4. Serum mean corpuscular volume (MCV)	No	-	-	No
5. Serum mean corpuscular haemoglobin (MCH)	No	-	-	No
6. Gastrointestinal disturbances as side effects	Yes	Described as gastrointestinal side effects.	-	No

Section 4. Data and analysis

DICHOTOMOUS OUTCOME	Intervention group		Control group	
	Number of events	Number of participants	Number of events	Number of participants
Gastrointestinal disturbances as side effects	4	53	9	53

State details if outcomes were only described in text or figures.

CONTINUOUS OUTCOME	Unit of measurement	Intervention group		Control group	
		n	Mean (SD)	n	Mean (SD)
Mean change of haemoglobin (Hb)	(g/dL)	53	8.565 (0.3809)	53	8.985 (1.6507)
Haemoglobin (Hb)	(g/dL)	53	8.67 (0.73)	53	9.44 (0.67)

State details if outcomes were only described in text or figures.

Section 5. Other information

	Description as stated in paper
Key conclusions of study authors	Ferrous sulfate has a better clinical response as compared to Iron polymaltose complex for treating iron deficiency anemia in children.
Results that you calculated using a formula	-
References to other relevant studies *(Did this report include any references to unpublished data from potentially eligible trials not already identified for this review? If yes, give list contact name and details)*	-
Correspondence required for further study information *(from whom, what and when)*	-

Sources:

Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011.Available from www.cochrane-handbook.org.