Study Eligibility & Data Collection Form

General Information

Study ID *(e.g. author name, year)*	Ozsurekci, 2015
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 forms 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)*	The purpose of this study was to compare the effectiveness of different oral iron preparations in children with iron deficiency anemia (IDA)
Design *(e.g. parallel, crossover, cluster)*	Parallel study of 3 treatment groups. Group I received ferrous sulfate (Fe-S); Group II received iron polymaltose complexes (Fe-OH-PM), and Group III received a single preparation of combined iron and zinc (Fe-Zn).
Unit of allocation *(by individuals, cluster/ groups or body parts)*	Individuals
Start & end dates	January 2008 till March 2009
Total study duration	1 year 3 months
Sources of funding *(including role of funders)*	-
Possible conflicts of interest *(for study authors)*	-

PARTICIPANTS	**Description** *(include information for each intervention or comparison group)*
Population description *(Company/companies; occupation)*	Children with iron deficiency anemia
Setting *(including location (city, state, country) and single center / multicenter)*	Pediatric outpatient clinic in Hecettepe University Faculty of Medicine, Pediatric Hematology Unit.
Inclusion criteria	1. Anemia was defined as hemoglobin (Hgb) below -2SD according to age and gender. 2. Iron deficiency (ID) was defined with serum iron, iron-binding capacity, ferritin, and transferrin saturation levels below the range for age and gender appropriates.
Exclusion criteria	1. Anemia due to other causes except IDA; Severe concurrent illness (cardiovascular, renal, hepatic) 2. Known hypersensitivity to ferrous or ferric preparations 3. Malignancy of any types 4. Children with thalassemia major 5. Sickle cell anemia or other haemoglobinopathies 6. Hemolytic anemia or aplastic or hypoplastic anemia.

Method of recruitment of participants *(e.g. phone, mail, clinic patients, voluntary)*	consecutive patients who attended the pediatric outpatient clinic.
Total no. randomized	60
Clusters *(if applicable, no., type, no. people per cluster)*	No
No. randomized per group *(specify whether no. people or clusters)*	Intervention: 21 Control: 19 (group III: 20)
No. missing *(if overall, e.g. exclusions & withdrawals, whether or not missing from analysis)*	15 dropped out during course of the study.
Reasons missing	Discontinuation of follow up
Baseline imbalances	No
Age	6 months to 15 years
Sex (proportion)	35 boys 25 girls
Race/Ethnicity	-
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** Low High Unclear	**Support for judgement** *(include direct quotes where available with explanatory comments)*	**Location in text or source** *(page, table)*
Random sequence generation *(selection bias)*	high	*were randomly included in Fe-S (group I), Fe-OH (group II), and Ferro Zinc(group III) in a consecutive fashion.*	Page2
Allocation concealment *(selection bias)*	unclear	*Not mentioned in full text*	-
Blinding of participants and personnel *(performance bias)*	unclear	Not mentioned in full text	-
Blinding of outcome assessment *(detection bias)*	low	Comment: Result are unlikely to be affected. *"Complete blood count (CBC), peripheral blood smear and reticulocyte levels were ordered on the same day"*	-
Incomplete outcome data *(attrition bias)*	low	No missing patients after randomization done.	-
Selective outcome reporting *(reporting bias)*	low	Study protocol not available. However, all pre-specified and expected outcomes of interest are reported	-
Other bias	low	No other bias detected	-

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 analyzed 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. Hemoglobin (Hb)	Yes	Mean 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 hemoglobin (MCH)	No	-	-	No
6. Gastrointestinal disturbances as side effects	No	-	-	No

Section 4. Data and analysis

DICHOTOMOUS OUTCOME	Intervention group		Control group	
	Number of events	Number of participants	Number of events	Number of participants
1.	-	-	-	-

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)
1. Hemoglobin (Hb)	(g/dL)	19	11.2 (0.5)	21	11.6(0.8)

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	*"each of the three iron preparations have been found to be effective in correcting IDA. There is no difference between the groups"* *"in all three groups, no severe side effects were observed"* *"both Fe-OH-PM and Fe-Zn preparations like Fe-S may be a choice in the treatment of children with IDA."*
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.