

# Intervention study to reduce the level of anaemia among infants

<b>Submission date</b> 24/01/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/05/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 19/05/2011	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Samia Halileh

**Contact details**  
Birzeit University  
Po Box 14  
Ramallah  
Palestine, State of  
-  
+972 (0)59 965 3889  
samia@birzeit.edu

## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Quasi study using two types of iron: a non-randomised controlled intervention trial

**Study objectives**

The introduction of ferrous sulphate at 6 months is suboptimal to the introduction of polymaltose complex iron preparation at 4 months in reducing the level of anaemia at 12 months. Iron preparation needs to be introduced earlier, at 4 months not 6 months and polymaltose complex is more palatable and has less gastrointestinal effects compared to ferrous sulphate.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Local Ethics Committee approved on the 1st September 2008

**Study design**

Quasi experimental non-randomised controlled intervention trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Anaemia

**Interventions**

1. Ferrous sulphate (control group)

1.1. Dose is 2 mg/kg/day, starting at 6 months of age, giving 3 bottles to last for 3 months for when the next follow up visit is due

1.2. Total duration is 6 months

1.3. Haemoglobin measured at 12 months

2. Iron polymaltose complex (intervention group)

2.1. Dose is 2 mg/kg/day, starting at 4 months of age, giving 2 bottles, 3 bottles and another 3 bottles to coincide with visits at 4, 6, 9 months

2.2. Total duration is 8 months

2.3. Haemoglobin measured at 12 months.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Haemoglobin level at 12 months

**Key secondary outcome(s))**

1. Feeding practices

2. Side effects of iron preparation

3. Compliance information

4. Family history of thalassaemia

4. Measures obtained via interview after the mother has performed the blood test for her child and before the results of the blood test, i.e., before her next visit to the clinic

**Completion date**

31/08/2010

## **Eligibility**

**Key inclusion criteria**

All infants attending the 4 and 6 months immunization

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

4 months

**Upper age limit**

6 months

**Sex**

All

**Key exclusion criteria**

1. Already taking iron
2. Pre-term or of low birth weight (only excluded if infants were already taking iron)
3. Mother refused consent
4. Does not have a file at the clinic

**Date of first enrolment**

01/11/2009

**Date of final enrolment**

31/08/2010

## **Locations**

**Countries of recruitment**

Palestine, State of

**Study participating centre**

**Birzeit University**  
Ramallah  
Palestine, State of  
-

## Sponsor information

### Organisation

Institute of Community and Public Health (Palestinian Territory)

## Funder(s)

### Funder type

Research organisation

### Funder Name

Swedish International Development Cooperation Agency (SIDA) (Sweden)

### Funder Name

Palestine Solidarity Association (PGS) (Sweden)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes