

# Iron and Folic acid v.s. Iron solely in the treatment of post partum anaemia, effects on haemoglobin and health status

Published: 18-07-2008

Last updated: 15-05-2024

our main objective is to determine whether additional folic acid to ferrous fumarate contributes to the increase of haemoglobin and the improvement of health status in post partum anaemia. Our second objective is to asses what the difference in...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32195

### Source

ToetsingOnline

### Brief title

Mothers strong as iron

### Condition

- Other condition
- Anaemias nonhaemolytic and marrow depression
- Postpartum and puerperal disorders

### Synonym

anemia, iron deficiency

### Health condition

kwaliteit van leven

### Research involving

Human

## Sponsors and support

**Primary sponsor:** TweeSteden ziekenhuis

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** anemia, folic acid, iron, postpartum

## Outcome measures

### Primary outcome

The main study parameter is the amount of increase of haemoglobin (mmol/l) four weeks after delivery in both anaemic sub-groups

### Secondary outcome

Secondary study parameters will be the difference in health status between the anaemic and non-anaemic groups, and between both anaemic sub-groups four weeks after delivery, measured using the RAND-36, CIS and EQ-5D questionnaires. And the observed difference in CHr between the anaemic and non-anaemic groups, and between both anaemic sub-groups four weeks after delivery.

## Study description

### Background summary

additional folic acid to ferrous fumarate in the treatment of anaemia could accelerate the increase of haemoglobin. Whether or not this has an effect on the health status of the patients is not known.

### Study objective

our main objective is to determine whether additional folic acid to ferrous fumarate contributes to the increase of haemoglobin and the improvement of health status in post partum anaemia. Our second objective is to asses what the

difference in health status is between anaemic and non-anaemic post partum women

## **Study design**

randomized controlled trial, and prospective cohort.

## **Intervention**

two main study groups will be constructed, each 150 patient, one non-anaemic group (haemoglobin  $\geq 6,5$  mmol/l) and one anaemic group (haemoglobin  $< 6,5$  mmol/l). Women in the anaemic study group will be randomised into two different treatment strategies, one group (n=75) receives three times daily a 200 mg tablet of ferrous fumarate and the other group (n=75) receives three times daily a 200 mg tablet of ferrous fumarate added with twice daily 0,5 mg of folic acid.

## **Study burden and risks**

The treatment of postpartum anaemia with ferrous fumarate is common and the addition of folic acid is nowadays dependent on the clinician. So far, there are no risks for the patients who participate in the study. Women with vitamin B12 deficiency could be at risk but are excluded from the study.

## **Contacts**

### **Public**

TweeSteden ziekenhuis

Postbus 90107  
5000 LA Tilburg  
Nederland

### **Scientific**

TweeSteden ziekenhuis

Postbus 90107  
5000 LA Tilburg  
Nederland

## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

1. Women aged > 18 years
2. 0-48 hours after delivery
3. Patients are in a clinical obstetric setting
4. Thorough grasp of the Dutch language
5. Informed consent acceptance

### Exclusion criteria

1. Pernicious anaemia (Vitamin B12 deficiency)
2. Packed cells infusion in the previous 3 months

## Study design

### Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Treatment

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated):	01-03-2008
Enrollment:	300
Type:	Anticipated

## Medical products/devices used

Product type:	Medicine
Brand name:	ferrous fumarate
Generic name:	ferrous fumarate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	folic acid
Generic name:	folic acid
Registration:	Yes - NL outside intended use

## Ethics review

Approved WMO	
Date:	29-08-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 25164  
Source: Nationaal Trial Register  
Title:

### In other registers

**Register**

EudraCT

CCMO

OMON

**ID**

EUCTR2008-000599-25-NL

NL21797.028.08

NL-OMON25164