

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

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	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