The efficacy of intermittent versus daily oral iron supplementation in anaemic pregnant women.

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To compare the efficacy, side effects and therapy compliance of intermittent (three times a week) versus daily oral iron supplementation for anaemia in pregnancy attributed to iron deficiency.

Ethical review	Approved WMO
Status	Pending
Health condition type	Anaemias nonhaemolytic and marrow depression
Study type	Interventional

Summary

ID

NL-OMON51243

Source
ToetsingOnline

Brief title
FER-IDIP trial (FER Intermittent vs Daily In Pregnancy)

Condition

- Anaemias nonhaemolytic and marrow depression
- Pregnancy, labour, delivery and postpartum conditions

Synonym
Anaemia

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: geen financiering beschikbaar

Intervention

Keyword: Anaemia, iron, oral, pregnancy

Outcome measures

Primary outcome

The main endpoint of the study is the difference in haemoglobin level from baseline to 6 weeks as a continuous variable. A multivariate analysis will be performed with gestational age/trimester at start iron supplementation, the duration of the treatment, use of other supplements, vegetarian diet and the use of proton pump inhibitors or H2 receptor antagonists.

Secondary outcome

The secondary endpoints are haemoglobin level at time of delivery, side effects, therapy compliance, term of delivery, birth weight, parenteral iron ante- or postpartum and blood transfusion postpartum.

Study description

Background summary

Iron deficiency anaemia in pregnancy is common and the standard treatment is iron supplementation once or twice daily. But there is no evidence for the optimal dose of iron supplementation in pregnancy. In non-pregnant women intermittent oral iron supplementation on alternate days is proven to have a similar effect on haemoglobin levels as iron supplementation daily with less side effects. In pregnancy the need and absorption of iron is physiologically higher. Therefore the optimal dose may differ from non-pregnant women.

The adverse effects of iron supplementation, which are mainly gastrointestinal effects, seem to be related to the dose of iron supplementation. These effects often already exist physiologically in pregnancy and may increase with the use of iron supplementation. Therefore, a lower dose would be preferable in pregnancy if the effectiveness is similar.

In this study intermittent dosage of iron supplementation three times a week will be compared to daily dosage in anaemic pregnant women due to iron deficiency. Our hypothesis is that intermittent oral iron supplementation is at least as effective as iron supplementation once daily and will give less adverse effects.

Study objective

To compare the efficacy, side effects and therapy compliance of intermittent (three times a week) versus daily oral iron supplementation for anaemia in pregnancy attributed to iron deficiency.

Study design

Single-centre, non-inferiority, open-label randomised controlled trial.

Intervention

One group will receive ferrous fumarate 200mg intermittent three times a week (for example on Monday, Wednesday and Friday) and one group will receive ferrous fumarate 200mg once daily.

Screening for anaemia during the pregnancy will be done according the local protocol in the first trimester and at a gestational age of 30 weeks. In women at risk for anaemia extra haemoglobin level will be measured at a gestational age of 20 weeks.

When a patient is eligible for the study she will be computer-randomised. Haemoglobin levels will be measured every 6 weeks after the start of the supplementation until the delivery. Side effects and therapy compliance will be evaluated with an interview.

Study burden and risks

In this study we follow the local protocol, which means subjects do not have additional hospital visits or blood tests. The only difference is the dosage of oral supplementation. Because ferrous fumarate is registered as a therapy for iron deficiency anaemia and both dosages are already used in daily practice there are no additional risks for the subjects.

If the haemoglobin level of a subject does not rise or when it is drops below 90.2 g/L (5.6 mmol/L) after at least 6 weeks of sufficient iron supplementation the subject will receive extra iron (higher dosage or intravenous) to lower the chance of a blood transfusion postpartum. This also corresponds with the local protocol and is standard care.

The benefit of this study is to gain more information about the optimal dosage of iron supplementation in pregnancy, taking into account its effectiveness and side effects. A lower dose would be preferable, because of the lower incidence of side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- Pregnant women of 18 years and older
- Iron deficiency anaemia (defined as: Anaemia (haemoglobin lower than cut-off value) AND mean corpuscular volume (MCV) 70-85 fl OR ferritin <30ug/L) OR mean corpuscular volume (MCV) < 70fl / hemoglobinopathy is ruled out.
- Adequate mental health
- Good command of the Dutch language
- No participation in other research with medication
- Informed consent

Exclusion criteria

- Start of iron supplementation at pregnancy duration > 37 weeks (because of the limited time to achieve an increase in haemoglobin).
- History of bariatric surgery, inflammatory bowel disease, coeliac disease or Helicobacter pylori infection (because of malabsorption of iron).
- Patients who received blood transfusion or parental iron supplementation during the 3 months prior to screening (because of the effect on the haemoglobin level).
- Patients with significant bleeding, blood donation or surgery during pregnancy (because of the effect on the haemoglobin level).
- Allergy for iron.
- Anaemia of other cause, such as a hemoglobinopathy.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2021
Enrollment:	58
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Ferrous fumarate

Generic name:	Ferrous fumarate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-11-2021
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2021-005393-26-NL
CCMO	NL77578.000.21