Effect of folic acid on heme iron absorption

Published: 21-01-2008
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To measure the effect of folic acid supplementation on heme iron absorption in vivo.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32198

Source
ToetsingOnline

Brief title
FAIR Study

Condition

- Other condition

Synonym
Iron deficiency anaemia

Health condition

Deficientie ziekten

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Absorption, Folic acid, Heme iron, Stable isotopes

Outcome measures

Primary outcome

The proportion of incorporation of 57Fe and 58Fe in red blood cells after 14

days will be the main outcome measure.

Secondary outcome

Not applicable

Study description

Background summary

Recently, for the first time an intestinal heme transporter (HCP1) was identified. In a later study, the same transporter was identified to be a proton-coupled folate transporter (PCFT) with a higher affinity for folates than for heme iron. Therefore, use of folic acid supplements may inhibit the absorption of heme iron.

Study objective

To measure the effect of folic acid supplementation on heme iron absorption in vivo.

Study design

The study is designed as a placebo controlled cross-over experiment.

Intervention

On two consecutive days, 4 mg of iron will be administered either as 32.4 mg of 57Fe protoporhyrin chloride or 32 mg of 58Fe protoporphyrin chloride with a spread on a bread roll. In addition, 1 mg of folic acid or placebo will be administered.

Study burden and risks

Participants are asked to visit the research site once for screening and four times after inclusion. At each occasion, 5-20 mL whole blood will be collected by venapuncture. Venapunctures occasionally lead to painful bruises which usually disappear within one week. Participants will be asked to fill out a questionnaire on relevant general and medical issues, and basic anthropometrics (weight, height) will be taken. During the study, 4 mg of iron labelled with stable isotopes (57Fe and 58Fe) will be administered orally as hemin at two consecutive days. Stable isotopes are non-hazardous to humans. The administered compounds will be subdued to standard toxicity procedures (purity, presence of heavy metals). All subjects will have a check-up of their iron status. Since included subjects will be marginally iron deficienct, participants will receive dietary advice in order to improve their iron status after the study and will be referred to their general practitioner on a voluntary basis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Body weight <60 kg, BMI 20-25 kg/m2, apparently healthy but marginal iron status (serum ferritin <25µg/L, Hb < 110 g/L).

Exclusion criteria

Severe anaemia or iron depletion (Hb < 70 g/L, serum ferritin < 12 µg/L). Use of drugs, unless no interference with iron/ folic acid metabolism or gastro-intestinal conditions such as paracetamol. Use of vitamin/mineral supplements containing iron or folic acid. Gastro-intestinal disorders, pregancy, lactation, unregular menstrual cycle.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2008
Enrollment:	17
Type:	Actual

Ethics review

Approved WMO

Date:	21-01-2008
Application type:	First submission

Review commission: METC Wageningen Universiteit (Wageningen)

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
CCMO	NL19912.081.07