The efficacy of a vitamin C rich guava fruit in improving iron absorption from mungbean based meals: a stable isotope study

Published: 16-11-2009
Last updated: 04-05-2024

To determine the efficacy of a local vitamin-C rich fruits in improving iron absorption from multiple mungbean based meals in Dutch women aged between 18-40 years.

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

Summary

ID

NL-OMON33466

Source
ToetsingOnline

Brief title
MuGuST

Condition

- Other condition

Synonym
iron absorption, iron bioavailability

Health condition

mineralen absorptie aandoeningen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: iron, pulses, stable isotopes, vitamin C

Outcome measures

Primary outcome

Assessment of the incorporation of 57Fe related to 58Fe into erythrocytes 14 d after administration and calculated based on isotope-dilution.

Secondary outcome

Whole blood will be collected at recruitment for the analysis of Hb, Hb type, serum ferritin (SF), transferrin receptor (TfR), C-reactive protein (CRP), erythropoietin (Epo), serum iron (SI), total iron binding capacity (TIBC), and transferrin saturation (TfSat). Anemia will be defined as a hemoglobin concentration < 120 g/L, and iron deficiency will be defined as an SF concentration < 12 µg/L.

Study description

Background summary

Iron deficiency (ID) and iron deficiency anemia (IDA) are the most prevalent micronutrient deficiencies among women and children in India. Anemia is associated with unfavourable birth outcomes in pregnant women and delayed or retarded cognitive and psychomotor development in children younger than 2 years of age. Non-heme iron constitute 91% of the total iron present in the Indian diet, and pulses are a significant dietary protein source. Fruits, green leafy vegetables, and animal products are infrequently consumed resulting in low iron, zinc and vitamin A intake. Mungbean (Vigna radiata L.) is the third most important pulse crop of India; it is a fairly good source of carbohydrates,

proteins, minerals e.g. calcium, iron and zinc. Several inhibitors in plant based diets limit iron bioavailability; these include phytic acid and polyphenols. Ascorbic acid is an important enhancer of iron absorption and has been shown to enhance non-heme iron absorption in humans.

Study objective

To determine the efficacy of a local vitamin-C rich fruits in improving iron absorption from multiple mungbean based meals in Dutch women aged between 18-40 years.

Study design

A stable-isotope study involving the incorporation of 57Fe and 58Fe iron isotopes into erythrocytes following consumption of labelled test meals and the determination of the isotopes concentrations 14 days post administration.

Intervention

Mungbean based test meals with labelled stable isotope solution, with or without a guava meal.

Study burden and risks

Participants will be invited for 3 blood samples will be collected from each subject within 31 days. The first sample will be taken on the first day of the intervention, the second after 14 days and the last sample on day 31 of the intervention. Subjects will consume 6 test meals within the first three days of the intervention. Consumption of mungbean meals and consumption of guava may prove unfamiliar because they have different flavours and textures than the subjects may be used to. Written informed consent will be obtained from all subjects. Participants will also have a medical questionnaire administered during the screening period. Venapuncture could cause local inflammation and little blood loss, however, this will be prevented by working with a qualified and experienced research nurse. .

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

Age 18-40 years
Body weight < 65 kg;
Non pregnant, non lactating and not planning to become pregnant
Apparetly healthy, free of chronic illnesses and not taking chronic medication.
No medication nor supplemental iron at time of entry into the study.
No intake of vitamin and mineral supplements in the last 2 weeks prior the study, or willigness to discontinue.
Subject has not made blood donation in the last 6 months
Subjects that in the past did not participate in studies with administration of stable isotope labels in the past (iron).

Exclusion criteria

Younger than 18 years of age and older than 40 years of age
Post menopausal
Using medicinal iron or related preparations
Body weight > 65kg
Pregnant or lactating
People consuming chronic medication
Use of vitamin and mineral supplements

Blood donation in the last 6 months
Subjects that in the past participated in studies with administration of stable isotope labels (iron).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2010
Enrollment:	12
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	16-11-2009
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	NL28661.081.09