Assessing the fractional absorption of iron from edible insects

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

Summary

ID

NL-OMON46965

Source
ToetsingOnline

Brief title
INSECTAIR

Condition

- Anaemias nonhaemolytic and marrow depression

Synonym
anaemia, Iron deficiency

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Wellcome Trust

Intervention

Keyword: Absorption, Edible insects, Iron, Isotope

Outcome measures

Primary outcome

The main study endpoint is the relative bioavailability (RBV) of iron.

Secondary outcome

Not applicable

Study description

Background summary

Sustainable diets are protective and respectful of biodiversity and ecosystems, culturally acceptable, accessible, and affordable; nutritionally adequate, safe and healthy; while optimizing natural and human resources. The fact that insects are a common food source for 2 billion people already provides excellent proof of its acceptability, especially in lower and middle income countries. In this project, we will carry out experiments to investigate the potential of insects as a source of iron when consumed as a common East African meal.

Study objective

The primary objective is to assess the relative bioavailability of iron from insect added to either a high- or low-phytate meal in humans and its potential to provide bioavailable iron. The secondary objective is to determine whether addition of edible insects enhances or inhibits the absorption of native or fortification iron from non-inhibitory or inhibitory meals

Study design

Single blind randomized partial Williams cross-over design

Intervention

Freeze dried insects labelled with 2mg 57Fe will be added to refined (non-inhibitory) maize porridge (test meal FeM-A) or to non-refined

(inhibitory) maize porridge (test meal FeM-D). Compared to two additional study test-meals (FeM-B and FeM-E) which will contain 6.5 mg $FeSO_4$ labelled with 3 mg $^{58}FeSO_4$ added to either non-refined/ refined maize porridge (inhibitory/ non-inhibitory food matrix respectively), the test meals will enable us to assess the relative bioavailability of iron from an insect-enriched low-phytate meal (non-inhibitory) or high-phytate (inhibitory) food matrix. The last two test meals (FeM-C and FeM-F) will contain half the amount of freeze dried non-labelled insects plus 5.8 mg $^{54}FeSO_4$ added to either refined (non-inhibitory) or non-refined (inhibitory) maize porridge. These meals will enable us to answer the question whether edible insects enhance/inhibit absorption of native or fortificant iron in inhibitory and/or non-inhibitory meals.

Study burden and risks

We do not anticipate that the experimental treatments will have any adverse effects. Though previous studies involving edible insects are rare, the European Food Safety Authority stated that house crickets are equivalent or better than soy in supporting growth, as was shown in a study using weaned rats (Committee 2015). Furthermore, although not systematically studied, house crickets as a source of food seem a healthy and safe product. The existence of 20.000 farms in Thailand producing insects for human consumption indicates crickets to be a safe food item. The food vehicle that will be used in this study (porridge made from maize flour) is widely consumed in many parts of Africa and Asia.

Participants will be expected to make eight visits to the research office. Blood collection will be carried out by trained, experienced study nurses and will be done on day 0 (screening time point), day 23, and day 39 (end point). On day 7, 8, 9, 23, 24 and 25 participants will consume a test-meal during breakfast and lunch time. During the screening visit, participants will be asked to fill a questionnaire about their general health. Anthropometric measurements will also be conducted. These data will contribute to baseline data in addition to the evaluation for participation. It is foreseen that the risks associated with participation in this study are negligible and the burden is minimal. In addition, because each participant will be their own control, disadvantages usually posed by being in the placebo group are not expected.

Experienced laboratory technicians and/or phlebotomists/nurses, using sterile equipment and techniques, will do venous blood collection. A total amount of 30 mL of blood will be collected (10 mL at screening, baseline and endpoint). The small risk of bleeding, infection and/or phlebitis after venepuncture will be explained to the participants before blood collection. We will comply with Dutch regulations for handling of biological specimens collected for research purposes.

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

Female; age 18-30 y; body weight <65 kg; marginal iron status (serum ferritin <25 ng/mL)

Exclusion criteria

Severe anaemia (Hb <80 g/L); elevated C-reactive protein (>5 mg/L); continuous use of medication (except contraception); any metabolic, gastro-intestinal, kidney or chronic disorder; pregnancy; supplement use <2 weeks before screening; blood transfusion/donation <6 months before screening; food allergy to crustaceans or mite.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-02-2018
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	14-04-2017
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	11-01-2018
Application type:	Amendment
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

ID: 21631
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL59400.081.16
OMON	NL-OMON21631