Bioavailability of Zinc from milk and rice using a stable isotope method

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Study I: To assess the bioavailability of Zinc from full cream UHT milk, fortified full cream UHT milk, a supplement, and raw milk.Study II: To assess the potential enhancing effect of milk on Zn absorption from intrinsically labelled rice (as a...

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

Summary

ID

NL-OMON40513

Source ToetsingOnline

Brief title Zinc bioavailability

Condition

• Other condition

Synonym absorption, bioavailability

Health condition

opname van micronutrienten in de darm

Research involving

Human

Sponsors and support

Primary sponsor: FrieslandCampina Innovation Centre **Source(s) of monetary or material Support:** FrieslandCampina

Intervention

Keyword: absorption, bioavailability, milk, zinc

Outcome measures

Primary outcome

Fractional absorption of Zn, as measured from isotope ratios in urine samples.

Secondary outcome

Secondary parameters:

- Inflammation markers: C-reactive protein (CRP), α-glycoprotein (AGP) in blood
- Zn status in blood
- Food Frequency Questionnaire

Only at baseline:

- Body weight and height

Study description

Background summary

Zinc deficiency is widespread globally. Some estimates indicate that 20% of the total world population has some degree of zinc deficiency. Zinc is one of the many essential nutrients found in milk. With a concentration of ~0.4 mg Zn per 100 g of milk, it forms an important source of Zn in dairy consuming populations such as in the Netherlands. There are indications in the literature that milk could enhance Zn absorption from plant-based foods, but this needs to be confirmed. To our knowledge, information on zinc absorption from regular dairy products in human subjects is scarce, as well as information on the

effect of enhancing factors (proteins) in milk.

Study objective

Study I: To assess the bioavailability of Zinc from full cream UHT milk, fortified full cream UHT milk, a supplement, and raw milk.

Study II: To assess the potential enhancing effect of milk on Zn absorption from intrinsically labelled rice (as a model for a phytate containing staple food)

Study design

Open, partially randomized, cross-over study.

Intervention

Study I: Intake of

1) Two times 400 ml full cream *Langlekker* milk, extrinsically labelled with 1 mg of 67Zn, consumed with a 1-hr interval;

2) Two times 200 ml Zn-fortified full cream *Langlekker* milk + 200 mL water (to keep volume the same), extrinsically labeled with 1 mg of 67Zn , consumed with a 1-hr interval;

3) Two times 400 ml water + Zn supplement, extrinsically labelled with 1 mg of 67Zn, consumed with a 1-hr interval.

4) Two times 400 ml raw milk

Study II: Intake of

1) Two times 45 g intrinsically 67Zn labelled rice + 300 mL of full cream *Langlekker* milk , consumed with a 1-hr interval;

2) Two times 45 g intrinsically 67Zn labelled rice + 300 mL of Zn fortified water, consumed with a 1-hr interval.

Each meal will contain \sim 4 mg of Zn. In between meals, subjects will receive an intravenous dose of 0.2 mg 70Zn, dissolved in 10 mL saline.

Study burden and risks

The risks associated with participation can be considered minimal. The intervention products and stable isotopes are safe for human use; apart from possible gastrointestinal discomfort from consuming 800 mL of milk, and no side effects are expected for the subjects (except rare complications of venepuncture and intravenous injection such as bleeding and bruising). The burden consists of 4 (study I) or 2 (study II) test days; on each test day the subjects consume one of the test products, undergo a venepuncture and an intravenous injection. Four days later subjects will collect a urine sample.

The subjects will not experience any health benefit from participation. Similar studies on Zn bioavailability from intrinsically labelled rice and millet have been performed in the past four years in a collaborative project between WU and ETH Zürich at study sites in China, Switzerland and Burkina Faso. Therefore, ample experience with these stable isotope studies is at hand.

Contacts

Public FrieslandCampina Innovation Centre

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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 years of age
- Body Mass Index (BMI): 19-25 kg/m2 and body weight: 60-70 kg

- No mineral and vitamin supplements two weeks prior to the 1st test day and during the whole duration of the study

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- Willing to abstain from blood donation during the study
- Voluntary participation
- Signed informed consent
- Willing to comply with the study procedures

Exclusion criteria

- Any metabolic, gastrointestinal, inflammatory or chronic disease/disorder (such as diabetes, anaemia, hepatitis, hypertension, cancer or cardiovascular diseases; according to the subjects own statement)

- Continuous/long-term medication during the whole study (except for contraceptives)
- Mineral or vitamin supplements during the 2 weeks prior to 1st test meal
- Lactose intolerance
- Alcohol consumption > 21 glasses/week
- Bad venous access
- Reported weight loss or gain of > 2kg in the last month before screening
- Reported strictly prescribed diet, vegan or macrobiotic
- Smoking

- Pregnant or lactating or the wish to become pregnant in the study period (a pregnancy test will be done before the last test day of Study I)

- Lack of safe contraception

- Earlier participation in any nutrition study using Zn stable isotopes as well as participation in any other clinical study within the last 30 days and during this study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2014
Enrollment:	38

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Actual

Ethics review

Approved WMO	
Date:	04-03-2014
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	18-04-2014
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO	
Date:	02-06-2014
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: 21804 Source: NTR Title:

In other registers

Register CCMO OMON

ID NL45256.081.13 NL-OMON21804