

Effect of Helicobacter infection on zinc and iron absorption

Submission date

14/12/2009

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

06/01/2010

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

06/01/2010

Condition category

Infections and Infestations

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Fondecyt 1080032

Study information

Scientific Title

Effect of Helicobacter infection on zinc and iron absorption: a single blind randomised controlled trial

Study objectives

1. Helicobacter pylori infection will have a negative effect on zinc absorption of adults who consume a wheat product fortified with iron and zinc
2. Zinc absorption from a wheat product fortified with zinc oxide will be significantly lower than that from the same product fortified with zinc sulfate in adults with Helicobacter pylori infection
3. Helicobacter pylori infection will have a negative effect on iron absorption of adults who consume a wheat product fortified with iron and zinc
4. Iron absorption from a wheat product fortified with ferrous fumarate will be significantly lower than that from the same product fortified with ferrous sulfate in adults with Helicobacter pylori infection
5. Iron and zinc absorption will be significantly lower in adults with hypochlorhydria compared to those with normal gastric acidity

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Chile, Institute of Nutrition and Food Technology (INTA) approved on the 20th June 2007 (ref: approval act No. 7)

Study design

Randomised controlled single-blind trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Helicobacter pylori infection

Interventions

The urea-C13 breath test will be used to assess Helicobacter pylori (HP) infection. A questionnaire will be used to determine gastrointestinal symptoms and all volunteers who indicate having symptoms will be excluded from the study.

Day 1:

Subjects will provide a fasting urine sample, which will be used as the baseline sample for zinc stable isotope enrichment analysis and as pre-intake sample for gastric pH measurement. Afterwards, they will randomly receive 100 g of bread fortified with either 5.5 mg of ferrous fumarate and 6 mg of zinc oxide or 5.5 mg of ferrous sulfate and 6 mg of zinc sulfate. Bread fortified with ferrous fumarate and zinc oxide will be labelled with 3 μCi of radioisotope ^{55}Fe and 0.5 mg of stable isotope ^{67}Zn and bread fortified with ferrous sulfate and zinc sulfate will be labelled with 1 μCi of radioisotope ^{59}Fe and 0.25 mg of stable isotope ^{70}Zn . A urine sample will be collected after breakfast consumption for gastric pH measurement.

Day 2:

Subjects will receive for breakfast the same bread they received on day 1 but labelled only with a stable isotope of zinc. Total dose of ^{67}Zn for 2 days of study will be 1 mg and total dose of ^{70}Zn for 2 days of study will be 0.5 mg. An additional 0.25 mg of zinc will be added to bread labelled with ^{70}Zn to maintain the dose effect of the isotope constant.

Day 3:

A 20 ml fasting blood sample will be collected to determine hemoglobin, serum iron, TIBC, transferrin saturation, serum ferritin, serum zinc, high sensitivity c-reactive protein, pepsinogen I and pepsinogen II concentrations. A 1 mg dose of stable isotope ^{68}Zn , as sulfate, will be administered intravenously immediately after blood collection. Subjects will receive for breakfast 100 g of bread fortified with those salts they did not receive on Days 1 - 2 and labelled with corresponding iron and zinc isotopes.

Day 4:

Subjects will receive for breakfast the same bread they received on Day 3 but labelled only with a stable isotope of zinc.

Days 7 - 11:

50 ml urine samples will be collected each morning and afternoon for zinc stable isotope enrichment analysis.

Day 17:

A second 20 ml blood sample will be obtained to assess circulating iron radioactivity.

Days 18 - 23:

Subjects will receive daily a proton pump inhibitor (20 mg/d omeprazole). 50 ml urine samples will be collected each morning and afternoon of Days 21 - 23 for zinc stable isotope enrichment analysis.

Day 24:

Subjects will provide a fasting urine sample, which will be used as the baseline sample for zinc stable isotope enrichment analysis and as pre-intake sample for gastric pH measurement. Furthermore, 20 ml of blood will be obtained to assess circulating iron radioactivity and ultrasensitive c-reactive protein, pepsinogen I and pepsinogen II concentrations. A 1 mg dose of stable isotope ^{68}Zn , as sulfate, will be administered intravenously immediately after blood collection. Subsequently, all subjects will receive 100 g of bread fortified with 5.5 mg of iron, as ferrous fumarate, and 6 mg of zinc, as zinc oxide, labelled with 3 μCi of radioisotope ^{55}Fe and 0.5 mg of stable isotope ^{67}Zn . A urine sample will be collected after breakfast consumption for gastric pH measurement.

Day 25:

Subjects will receive for breakfast the same bread they received on Day 21 but labelled only with a stable isotope of zinc.

Days 28 - 32:

50 ml urine samples will be collected each morning and afternoon for zinc stable isotope enrichment analysis.

Day 38:

20 ml of blood will be collected to assess circulating iron radioactivity.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ferrous sulfate, zinc sulfate, ferrous fumarate, zinc oxide

Primary outcome measure

Assessed on days 17 and 38 of the study:

1. Fractional iron absorption, assessed by Eakins and Brown's double-isotope technique
2. Fractional zinc absorption, determined from the ratio of urinary enrichment of oral doses (^{67}Zn and ^{70}Zn) as a proportion of urinary enrichment of intravenous dose (^{68}Zn)

Secondary outcome measures

1. Intragastric pH, assessed by the urine acid output test, assessed on days 1 and 24 of the study
2. Pepsinogen I and pepsinogen II will be determined by radioimmunoassay, assessed on day 3 of the study. Haemoglobin, serum iron, TIBC and transferrin saturation, serum ferritin and serum zinc, assessed on day 3 of the study
7. High sensitivity C-reactive protein, assessed on day 3 of the study

Overall study start date

01/04/2007

Completion date

31/12/2010

Eligibility

Key inclusion criteria

1. Asymptomatic adults
2. Aged 35 - 45 years (women) and aged 25 - 45 years (men)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

96

Key exclusion criteria

Gastrointestinal symptoms

Date of first enrolment

01/04/2007

Date of final enrolment

31/12/2010

Locations**Countries of recruitment**

Chile

Study participating centre

Avenida El Libano 5524

Santiago

Chile

7830489

Sponsor information**Organisation**

University of Chile, Institute of Nutrition and Food Technology (INTA) (Chile)

Sponsor details

Avenida El Libano 5540

Macul

Santiago

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7830489

Sponsor type

University/education

Website

<http://www.inta.cl>

ROR

Funder(s)

Funder type

Government

Funder Name

Fund for Scientific and Technological Chile (Fondo de Desarrollo Científico y Tecnológico [FONDECYT]) (Chile) (ref: 1080032)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration