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Effect of Helicobacter infection on zinc and iron absorption

Submission date	Recruitment status	[_] Prospectively registered
14/12/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/01/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/01/2010	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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 55Fe and 0.5 mg of stable isotope 67Zn and bread fortified with ferrous sulfate and zinc sulfate will be labelled with 1 µCi of radioisotope 59Fe and 0.25 mg of stable isotope 70Zn. 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 67Zn for 2 days of study will be 1 mg and total dose of 70Zn for 2 days of study will be 0.5 mg. An additional 0.25 mg of zinc will be added to bread labelled with 70Zn 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 68Zn, as sulfate, will be administered intravenously immediately after blood colection. 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 68Zn, 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 55Fe and 0.5 mg of stable isotope 67Zn. 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(s)
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 (67Zn and 70Zn) as a proportion of urinary enrichment of intravenous dose (68Zn)

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

ROR
https://ror.org/047gc3g35

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes