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Re-evaluation of the upper level of intake for zinc using novel molecular biomarkers of copper status

Submission date	Recruitment status
31/05/2007	No longer recruiting
Registration date	**Overall study status**
12/06/2007	Completed
Last Edited	**Condition category**
08/05/2013	Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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
N/A

Study information

Scientific Title

Acronym
ZIP (Zinc Intake Project)

Study objectives
High intakes of zinc reduce copper status in healthy children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from:
1. Health Canadas Research Ethics Board on the 2nd September 2005 (ref: REB-2004-0057)
2. University of Guelph Research Ethics Board on the 4th May 2005 (ref: REB# 05JA018)

Study design
Randomised, double-blind, placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Decreased copper status

Interventions
Each boy (25 per group) will take two zinc tablets per day (one in the morning with breakfast and one in the evening with dinner) for 120 days that will provide a total of either 0 (placebo group), 5, 10 or 15 milligrams of supplemental zinc per day.

Subjects will be measured and weighed at the beginning (Day 0), middle (Day 60) and end (Day 120) of the study. Blood and urine samples will be collected at Day 0, 60 and 120 to assess general health of the boys and determine zinc and copper status.

The amounts of zinc and copper obtained by diet will be assessed by a three-day food record (to be completed by the caregivers of the boys at the beginning and end of the study) and food frequency questionnaire (to be completed by the caregivers of the boys at the end of the study).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Zinc

Primary outcome measure
Effects of different levels of zinc intake on copper status will be determined by measuring the following indices of copper nutriture:
1. Expression of erythrocyte copper chaperone for Cu/Zn superoxide dismutase
2. Plasma copper concentration
3. Plasma ceruloplasmin activity
4. Erythrocyte Cu/Zn superoxide dismutase activity

Secondary outcome measures
Effects of different levels of zinc intake on:
1. Height
2. Weight
3. Complete blood counts
4. Lipid profile

Overall study start date
01/02/2007

Completion date
01/09/2008

Eligibility

Key inclusion criteria
1. Healthy boys 7 to 8 years of age
2. Boys not taking a mineral supplement and have not taken a mineral supplement three months prior to commencing the study
3. Boys not taking sodium fluoride or aspirin
4. Boys living in Guelph, Ontario vicinity
5. Informed consent by the caregivers of the boys
6. Assent by the boys

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
8 Years

Sex
Male

Target number of participants
100

Key exclusion criteria
Individuals not fulfilling the above inclusion criteria.

Date of first enrolment
01/02/2007

Date of final enrolment
01/09/2008

Locations

Countries of recruitment
Canada

Study participating centre
HPFB, Nutrition Research Division
Ottawa
Canada
K1A 0L2

Sponsor information

Organisation
Health Canada (Canada)

Sponsor details
Sir Frederick G. Banting Research Centre
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Sponsor type
Government

Website
http://www.hc-sc.gc.ca/

ROR
https://ror.org/05p8nb362

Funder(s)

Funder type
Government

Funder Name
Health Canada (Canada) - Nutrition Research Division (ref: project # 4500550)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2013		Yes	No