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Assessment of dietary zinc intake and molecular biomarkers of zinc status in UK women

Submission date
08/08/2013

Recruitment status
No longer recruiting

Registration date
19/09/2013

Overall study status
Completed

Last Edited
13/12/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dietary zinc is important for human growth, development and immunity. Minor zinc deficiency is common but difficult to assess. While blood plasma zinc has been successfully used to assess how people respond to zinc supplementation, it is a weak indicator for individual zinc status. In the UK, a lot of young women are not getting the enough zinc through their diet. Unlike many other minerals, the body has no stores of zinc to use when intakes are low. Research has shown that zinc-responsive genes can monitor zinc status. The aim of this study is to assess both the dietary intake of zinc and indicators in the body of zinc status in vegetarian and non-vegetarian women before and after supplementation.

Who can participate?
Women living in the UK aged 19-45

What does the study involve?
The study looks at two dietary groups of women: vegetarian and non-vegetarian. Within their dietary groups, women are randomly allocated to receive either zinc or placebo (dummy). For each visit participants come in without having eaten or drunk anything apart from water and are asked not to brush their teeth. A trained doctor takes two blood samples at the start of the study and on the 7th and 14th days of the study. In addition, participants provide a saliva sample at each visit for further analysis. They are given a food frequency questionnaire to complete on your first visit, and are asked to recall what they ate the day before attending the clinic at each visit.

What are the possible benefits and risks of taking part?
Participants receive information about their current zinc status and when they complete the study they are offered a £10 Starbucks gift voucher. Once all data has been analysed, personalised feedback is provided. There are no risks for supplementation of zinc at this level. Women in many countries have similar intakes of zinc. Participants may suffer from bruising from the blood sampling and embarrassment from giving a saliva sample.

Where is the study run from?
University of Surrey, Guildford, FHMS Clinical Investigation Unit (CIU) (UK)

When is the study starting and how long is it expected to run for?
The study started in November 2011 and recruited up until May 2012

Who is funding the study?
General Authority for Health Services for the Emirate of Abu Dhabi

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Assessment of dietary zinc intake and molecular biomarkers of zinc status in UK women: a double-blinded randomised case-controlled study

Study objectives
1. Vegetarian women will have lower intakes of dietary zinc than non-vegetarian women
2. There will be no significant difference in serum zinc levels between the two groups in response to supplementation
3. The expression of zinc transports will respond to zinc supplementation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Faculty of Health and Medical Sciences (FHMS) Ethics Committee, 29/03/2011, ref: EC/2011/02

Study design
Double-blinded randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Zinc deficiency

Interventions
There are two dietary groups: vegetarian and non-vegetarian. There are two treatment-sub-groups:
1. 15 mg/day of zinc as zinc gluconate
2. Placebo
Total duration of intervention: 2 weeks
Route of administration: by mouth for both supplement and placebo.
Excess pills were provided and a pill count was completed after the week of supplementation in order to monitor compliance.

Intervention Type
Supplement

Primary outcome measure
1. Zinc transporter (SLC30A1 and SLC39A3) transcript levels in blood and saliva.
2. Serum concentrations of zinc by blood samples

Secondary outcome measures
Dietary intakes of zinc, phytate and other nutrients. Zinc supplementation was measured by blood and saliva.

Overall study start date

01/05/2011

Completion date
01/12/2013

Eligibility

Key inclusion criteria
1. Healthy females
2. British residents
3. Aged between 19-45 years

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
30: 15 vegetarian (7 cases, 8 controls) and 15 non-vegetarian (7 cases, 8 controls) women

Key exclusion criteria
1. Pregnant or breastfeeding now or in last 6 months
2. History of alcohol abuse
3. Current of recent (last 2 months) use of vitamin, mineral supplements
4. History of eating disorder
5. Consumption of meat, poultry or fish in the last year (for vegetarian group)
6. Recent traumas or surgery

Date of first enrolment
01/05/2011

Date of final enrolment
01/05/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Surrey
Guildford

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Sponsor information

Organisation
University of Surrey (UK)

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Sponsor type
University/education

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Government

Funder Name
General Authority for Health Services for the Emirate of Abu Dhabi

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