

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

<b>Submission date</b> 08/08/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/09/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/12/2017	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?  
Dr J. Bernadette Moore  
j.b.moore@surrey.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr J. Bernadette Moore

**Contact details**  
22 AY 03  
FHMS  
University of Surrey  
Guildford  
United Kingdom  
GU2 7XH  
+44 (0)1483 686405  
j.b.moore@surrey.ac.uk

## Additional identifiers

## 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

### **Study type(s)**

Diagnostic

### **Health condition(s) or problem(s) studied**

Zinc deficiency

### **Interventions**

There are two dietary groups: vegetarian and non-vegetarian. There are two treatment-subgroups:

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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

1. Pregnant or breastfeeding now or in last 6 months
2. History of alcohol abuse
3. Current or 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**

United Kingdom

England

**Study participating centre**

**University of Surrey**

Guildford

United Kingdom

GU2 7XH

**Sponsor information****Organisation**

University of Surrey (UK)

**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**

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration