ISRCTN96013840 https://doi.org/10.1186/ISRCTN96013840

# Factors affecting serum zinc concentrations in the U.S. population

**Submission date**
26/12/2017

**Recruitment status**
No longer recruiting

**Registration date**
09/01/2018

**Overall study status**
Completed

**Last Edited**
28/06/2018

**Condition category**
Other

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

## Plain English summary of protocol

Background and study aims
Zinc is a nutritionally essential trace mineral required for many biological functions. Marginal or moderate zinc deficiency may be widespread and has negative consequences on health. Although serum (blood) zinc is not considered a reliable indicator of the zinc status of an individual, it is the most widely used and available indicator of risk of zinc deficiency in populations. Moreover, serum zinc is the only indicator of zinc status for which adequate reference data and suggested lower cutoff values are available. However, caution is advised when interpreting serum zinc concentrations as many factors have been identified to affect serum zinc independent of an individual's zinc status, such as meal consumption, time of day, and inflammation and infection. The cutoffs for serum zinc were established based on serum zinc values obtained from the second National Health and Nutrition Examination Survey (NHANES) in the U.S. (1976-1980). In subsequent years serum zinc was excluded from NHANES and was not re-introduced as a biochemical measurement until the 2011-2012 survey cycle. The aim of this study is to re-evaluate serum zinc concentrations in the U.S. population and to find factors affecting serum zinc using data from NHANES 2011-12 and 2013-14.

Who can participate?
Data from people aged 6 and over participating in NHANES, 2011-2014

What does the study involve?
Previously collected data is extracted from the NHANES database. The database is accessible to the public through the Centers for Disease Control website (National Health and Nutrition Examination Survey; http://cdc.gov/NCHS/nhanes.htm) and does not contain any personal identifiers. Serum zinc and dietary zinc intake are determined and factors affecting serum zinc are identified. The prevalence of low serum zinc in the U.S. is calculated.

What are the possible benefits and risks of participating?
This study will provide data on factors that affect serum zinc concentrations and will inform serum zinc reference values.

Where is the study run from?
U.S. Army Research Institute of Environmental Medicine (USA)

When is the study starting and how long is it expected to run for?
January 2011 to December 2014

Who is funding the study?
1. Medical Research and Materiel Command (USA)
2. Department of Defense Center Alliance for Nutrition and Dietary Supplement Research (USA)

Who is the main contact?
Dr Stephen Hennigar

# Contact information

### Type(s)
Scientific

### Contact name
Dr Stephen Hennigar

### Contact details
10 General Greene Ave.
Natick
United States of America
01760

# Additional identifiers

### Protocol serial number
R11-01

# Study information

### Scientific Title
Factors affecting serum zinc concentrations in the U.S. population: National Health and Nutrition Examination Survey (2011-2014)

### Study objectives
Serum zinc concentration is frequently used to assess zinc status in populations. Cutoffs for serum zinc were developed based on data from National Health and Nutrition Examination Survey (NHANES) II in 1976-80, but until recently (2011-12) serum zinc was not included in NHANES. The objective of this study was to evaluate serum zinc concentration in the U.S. population and determine factors affecting serum zinc using NHANES 2011-14.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. The National Center for Health Statistics Research Ethics Review Board approved the use of human subjects for NHANES studies
2. The USARIEM Human Use Review Committee determined obtaining unidentifiable

information did not constitute human subjects research and therefore did not require full human use review on 13/10/2010

### Primary study design
Observational

### Study design
Observational epidemiological study

### Study type(s)
Other

### Health condition(s) or problem(s) studied
Serum zinc concentration

### Interventions
Data were extracted from a preexisting public database – a nationally representative survey of the US population, the National Health and Nutrition Examination Survey (NHANES). All data used have previously been collected. The database is accessible to the public through the Centers for Disease Control website on the World Wide Web (National Health and Nutrition Examination Survey; http://cdc.gov/NCHS/nhanes.htm) and does not contain any personal identifiers. Standard statistical methods for analysis of weighted population NHANES datasets were employed, including multiple regression modeling.

Serum zinc was determined in males and females ≥6 y using NHANES 2011-2014 (n=4,347). Dietary zinc intake was determined and factors affecting serum zinc were identified while controlling for sex, age, fasting status, and time of blood draw. Odds ratios were calculated to identify factors associated with risk of being below the cutoff for serum zinc and the prevalence of low serum zinc in the U.S. was calculated.

### Intervention Type
Other

### Primary outcome(s)
Serum zinc concentration in the U.S. population and factors affecting serum zinc using the National Health and Nutrition Examination Survey 2011-2014

### Key secondary outcome(s)
Prevalence of low serum zinc in the U.S. population using serum zinc concentrations from the National Health and Nutrition Examination Survey 2011-2014

### Completion date
31/12/2014

## Eligibility

### Key inclusion criteria
1. Data from those aged ≥ 6 years participating in NHANES, 2011-2014 with serum zinc values (~1 /3 of sample) were used for these analyses
2. Data for pregnant (n=34) or lactating females (n =20) were separated and analyzed separately

**Participant type(s)**
All

**Healthy volunteers allowed**
No

**Age group**
All

**Sex**
All

**Key exclusion criteria**
Volunteers without a serum zinc value were excluded from this analysis

**Date of first enrolment**
01/01/2011

**Date of final enrolment**
31/12/2014

# Locations

**Countries of recruitment**
United States of America

**Study participating centre**
**U.S. Army Research Institute of Environmental Medicine**
United States of America
01760

# Sponsor information

**Organisation**
U.S. Army Research Institute of Environmental Medicine

**ROR**
https://ror.org/00rg6zq05

# Funder(s)

**Funder type**
Government

**Funder Name**
Medical Research and Materiel Command

**Alternative Name(s)**
U.S. Army Medical Research and Materiel Command, US Army Medical Research and Materiel Command, MRMC, USAMRMC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United States of America

**Funder Name**
Department of Defense Center Alliance for Nutrition and Dietary Supplement Research

# Results and Publications

**Individual participant data (IPD) sharing plan**
De-identified data are available at the participant level for all study participants in a publically available repository (National Health and Nutrition Examination Survey; http://cdc.gov/NCHS/nhanes.htm).

**IPD sharing plan summary**
Stored in repository

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/08/2018 | | Yes | No |