

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jun 2026

### Clinical trial of the effect of zinc supplementation compared with the placebo on metabolic profiles in pregnant women at risk for intrauterine growth restriction

#### Protocol summary

##### Study aim

The aim of this study is to determine the effects of zinc supplementation on metabolic profiles in pregnant women at risk for intrauterine growth restriction

##### Design

Design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive zinc supplements (n=30) or placebo (n=30).

##### Settings and conduct

Among pregnant women at risk for intrauterine growth restriction referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 10 weeks after the intervention. At the beginning and the end of the intervention: 10 weeks

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women at risk for intrauterine growth restriction, aged 18 to 40 years. Exclusion criterion: The consumption of zinc supplements throughout past 3 months, hyper- and hypothyroidism, urinary tract infection, smoking and also having liver or kidney diseases.

##### Intervention groups

Intervention group: zinc supplements, 100 µg, daily, for 10 weeks orally. Control group: Placebo once a day for 10 weeks orally.

##### Main outcome variables

Total Antioxidant Capacity and Pulsatility Index (primary outcomes) and lipid profiles, markers of insulin metabolism and inflammatory factors (secondary outcomes) will be quantified at study baseline and end-

of-trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170513033941N33**

Registration date: **2018-06-03, 1397/03/13**

Registration timing: **retrospective**

Last update: **2019-09-24, 1398/07/02**

Update count: **1**

##### Registration date

2018-06-03, 1397/03/13

##### Registrant information

##### Name

Mohammadreza Sharif

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5546 3378

##### Email address

ostadmohammadi-vr@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-06, 1396/12/15

##### Expected recruitment end date

2018-04-04, 1397/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Clinical trial of the effect of zinc supplementation compared with the placebo on metabolic profiles in pregnant women at risk for intrauterine growth restriction

**Public title**

Effect of zinc supplementation in treatment of pregnant women at risk for intrauterine growth restriction

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Inclusion criteria: Pregnant women at risk for intrauterine growth restriction. Individuals aged 18 to 40 years.

**Exclusion criteria:**

The consumption of zinc supplements throughout past 3 months Hyper- and hypothyroidism Urinary tract infection Smoking Having liver or kidney diseases

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

At study baseline, after balanced randomisation, subjects will be divided into two groups to receive supplement or placebo. Randomization will be done by the use of computer-generated random numbers.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

1771844351

**Approval date**

2018-03-05, 1396/12/14

**Ethics committee reference number**

IR.KAUMS.MEDNT.REC.1396.117

**Health conditions studied****1****Description of health condition studied**

Pregnancy

**ICD-10 code**

094

**ICD-10 code description**

Sequelae of complication of pregnancy, childbirth and the puerperium

**Primary outcomes****1****Description**

Total antioxidant

**Timepoint**

At the beginning of the study and after 10 weeks of intervention

**Method of measurement**

Spectrophotometry

**2****Description**

pulsatility index

**Timepoint**

At the beginning of the study and after 10 weeks of intervention

**Method of measurement**

Sonography

**Secondary outcomes****1****Description**

Insulin

**Timepoint**

At the beginning of the study and after 10 weeks of intervention

**Method of measurement**

Elisa kit

## 2

### **Description**

hs-CRP

### **Timepoint**

At the beginning of the study and after 10 weeks of intervention

### **Method of measurement**

Elisa kit

## 3

### **Description**

Nitric oxide

### **Timepoint**

At the beginning of the study and after 10 weeks of intervention

### **Method of measurement**

Spectrophotometry

## 4

### **Description**

Triglycerides

### **Timepoint**

At the beginning of the study and after 10 weeks of intervention

### **Method of measurement**

Enzymatic kit

## 5

### **Description**

Cholesterol

### **Timepoint**

At the beginning of the study and after 10 weeks of intervention

### **Method of measurement**

Enzymatic kit

## 6

### **Description**

Glutathione

### **Timepoint**

At the beginning of the study and after 10 weeks of intervention

### **Method of measurement**

Spectrophotometry

## 7

### **Description**

Malondialdehyde

### **Timepoint**

At the beginning of the study and after 10 weeks of intervention

### **Method of measurement**

Spectrophotometry

## 8

### **Description**

HDL-cholesterol

## **Timepoint**

At the beginning of the study and after 10 weeks of intervention

## **Method of measurement**

Enzymatic kit

## **Intervention groups**

### 1

#### **Description**

Intervention group: zinc supplement, 100 µg, daily, for 10 weeks orally

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Placebo, daily, for 10 weeks orally.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Naghavi Clinic

##### **Full name of responsible person**

Dr. Elahe Mesdaghinia

##### **Street address**

Ghotbe Ravandi Boulevard, Kashan

##### **City**

Kashan

##### **Province**

Isfahan

##### **Postal code**

1771844351

##### **Phone**

+98 31 5546 3378

##### **Email**

asemi\_z@kaums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Kashan University of Medical Sciences

##### **Full name of responsible person**

Gholamali Hamidi

##### **Street address**

Ghotbe Ravandi Boulevard, Kashan

##### **City**

Kashan

##### **Province**

Isfahan

##### **Postal code**

1771844351

**Phone**  
+98 31 5546 3378

**Email**  
Gholamali\_h@kaums.ac.ir

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Kashan University of Medical Sciences

**Proportion provided by this source**  
100

**Public or private sector**  
Public

**Domestic or foreign origin**  
Domestic

**Category of foreign source of funding**  
*empty*

**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences

**Full name of responsible person**  
Zatollah Asemi

**Position**  
PhD of Nutrition

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Nutrition

**Street address**  
Ghotbe Ravandi Boulevard, Kashan

**City**  
Kashan

**Province**  
Isfahan

**Postal code**  
1771844351

**Phone**  
+98 31 5546 3378

**Fax**

**Email**  
asemi\_z@kaums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences

**Full name of responsible person**  
Zatollah Asemi

**Position**  
PhD of Nutrition

**Latest degree**

Ph.D.

**Other areas of specialty/work**  
Nutrition

**Street address**  
Ghotbe Ravandi Boulevard, Kashan

**City**  
Kashan

**Province**  
Isfahan

**Postal code**  
1771844351

**Phone**  
+98 31 5546 3378

**Fax**

**Email**  
asemi\_z@kaums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences

**Full name of responsible person**  
Zatollah Asemi

**Position**  
PhD of Nutrition

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Nutrition

**Street address**  
Ghotbe Ravandi Boulevard, Kashan

**City**  
Kashan

**Province**  
Isfahan

**Postal code**  
1771844351

**Phone**  
+98 31 5546 3378

**Fax**

**Email**  
asemi\_z@kaums.ac.ir

**Web page address**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to

make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available