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

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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
Isfehan

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
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Isfehan
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1771844351
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+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
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Phone
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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
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Person responsible for updating data

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Ph.D.
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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