Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of the effect of combined omega-3 and vitamin E supplementation on pregnancy outcomes in gestational diabetes

Protocol summary

Study aim
The aim of the current study is to evaluate the effects of combined omega-3 and vitamin E supplementation on pregnancy outcomes in gestational diabetes.

Design
Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct
Population and sample size: 60 patients with GDM among pregnant women of eligible and referred to Kosar Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: In the current study, pregnant women aged 18-40 years with gestational diabetes (GDM) at 24-28 week gestation will be included. Exclusion criteria: Placenta abruption, preeclampsia, eclampsia, hypo- and hyperthyroidism, urinary tract infection, smokers, kidney or liver diseases.

Intervention groups
Intervention: Patients will be assigned to receive either omega-3 plus vitamin E supplements (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables
Outcomes: Biomarkers of oxidative stress and inflammation (primary outcomes) and pregnancy outcomes (secondary outcome).

General information

Reason for update
Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information
IRCT registration number: **IRCT201507035623N47**
Registration date: **2015-07-19, 1394/04/28**
Registration timing: **retrospective**

Last update: **2019-11-10, 1398/08/19**
Update count: **1**

Registration date
2015-07-19, 1394/04/28

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date
2015-06-09, 1394/03/19

Expected recruitment end date
2015-07-19, 1394/04/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of combined omega-3 and vitamin E supplementation on pregnancy outcomes in gestational diabetes

Public title
Effect of supplementation in treatment of gestational diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women aged 18-40 years Diagnosed with GDM at 24-28 week gestation
Exclusion criteria:
Placenta abruption Preeclampsia Eclampsia Hypo- and hyperthyroidism Urinary tract infection Smokers Kidney or liver 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 and after stratification for pre-intervention BMI and weeks of gestation, subjects will be randomly divided into two groups to take combined omega-3 and vitamin E supplementation (n = 30) or placebo (n = 30). 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. Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the gynecology clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules. Supplements and placebos capsules are similar in shape and size.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethicc's committee of Arak University of Medical Sciences
Street address
Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2015-06-08, 1394/03/18
Ethics committee reference number
IR.ARAKMU.REC.1394.37

Health conditions studied

1

Description of health condition studied
Gestational diabetes
ICD-10 code
O24.9
ICD-10 code description
Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description
Total antioxidant capacity
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

2

Description
Glutathione
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

3

Description
Malondialdehyde
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

4

Description

Hs-CRP
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa

5

Description
Nitric oxide
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

Secondary outcomes

1

Description
Newborn length
Timepoint
The first 24 h after birth
Method of measurement
Scale

2

Description
Newborns' weight
Timepoint
The first 24 h after birth
Method of measurement
Scale

3

Description
Polyhydramnios
Timepoint
After the intervention
Method of measurement
Sonography

4

Description
Newborn's head circumference
Timepoint
Delivery time
Method of measurement
Tape

5

Description
Newborn's bilirubin
Timepoint
Delivery time
Method of measurement
Enzymatic kit

6

Description
Apgar score
Timepoint
Delivery time
Method of measurement
Clinical observation

7

Description
Preterm delivery
Timepoint
After delivery
Method of measurement
Medical record

8

Description
Maternal pre-eclampsia
Timepoint
After delivery
Method of measurement
Medical record

9

Description
Maternal hospitalization
Timepoint
After delivery
Method of measurement
Medical record

10

Description
Newborns' hospitalization
Timepoint
After delivery
Method of measurement
Medical record

Intervention groups

1

Description
Intervention group: Combined omega-3 and vitamin E pearl, 1000 mg omega-3 and 400 IU vitamin E, daily, for 6 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo pearl, daily, for 6 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kosar Clinic

Full name of responsible person
Mehri Jamilian

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Emam Khomeyni Avenue, Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person
Mohammad Rafiee

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice chancellor for research, Arak 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

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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