

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

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asemi_z@kaums.ac.ir

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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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