

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial of the effect of combined omega-3 fatty acids and vitamin D supplementation compared with the placebo on metabolic profiles and pregnancy outcomes in patients with gestational diabetes

Protocol summary

Study aim

The aim of this study is to determine the effects of combined omega-3 fatty acids and vitamin D supplementation on metabolic profiles and pregnancy outcomes in patients with gestational diabetes.

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: 120 patients with gestational diabetes of eligible and referred to Alavi Clinic affiliated to Ardabil University of Medical Sciences, Ardabil, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with gestational diabetes and aged 18 to 40 years will be included in this study.

Exclusion criteria: Taking omega-3 fatty acids supplements, insulin therapy, placenta abruption, pre-eclampsia, eclampsia, hypo and hyperthyroidism and Smokers

Intervention groups

Intervention: Patients will be assigned to receive either combined omega-3 fatty acids or vitamin D (n=30), omega-3 fatty acids (n=30), vitamin D supplements (n=30) and placebo (n=30). Combined omega-3 fatty acids and vitamin D, omega-3 fatty acids, vitamin D supplements and placebos capsules are similar in shape and size.

Main outcome variables

Outcomes: Inflammatory factors (primary outcomes), and oxidative stress factors and pregnancy outcomes will be quantified at study baseline and at the end of the trial.

General information

Reason for update

Unfortunately, due to carelessness, update request was done after publishing paper. In addition, the requested changes are in accordance with the approved proposal and with the coordination of Vice Chancellor of Research of Ardabil University of Medical Sciences

Acronym

IRCT registration information

IRCT registration number: **IRCT201701305623N106**

Registration date: **2017-02-09, 1395/11/21**

Registration timing: **retrospective**

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

Update count: **1**

Registration date

2017-02-09, 1395/11/21

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical Sciences

Expected recruitment start date

2016-09-08, 1395/06/18

Expected recruitment end date

2016-11-08, 1395/08/18

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 fatty acids and vitamin D supplementation compared with the placebo on metabolic profiles and pregnancy outcomes in patients with gestational diabetes

Public title

Effect of supplementation in treatment of patients with gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with gestational diabetes Age range of 18 to 40 years

Exclusion criteria:

Taking omega-3 fatty acids supplements Insulin therapy Placenta abruption Pre-eclampsia Eclampsia Hypo and hyperthyroidism Smokers

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: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the gynecology clinics, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules. Participants, investigators or the assessors of the outcomes are unaware of the study groups. The appearance of the placebo capsule is indistinguishable in color, shape, size, and packaging, smell and taste from vitamin D and omega-3 fatty acids capsules.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences

City

Ardabil

Province

Ardabil

Postal code

5613974156

Approval date

2016-09-07, 1395/06/17

Ethics committee reference number

IR.ARUMS.REC.1395.35

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

Gestational diabetes

ICD-10 code

E28.2

ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

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

Hs-CRP

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Elisa kit

2**Description**

Nitric oxide

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Total antioxidant

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

Glutathione

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Newborns' weight

Timepoint

The first 24 h after birth

Method of measurement

Scale

5

Description

Newborn length

Timepoint

The first 24 h after birth

Method of measurement

Girth measuring tape

6

Description

Polyhydramnios

Timepoint

After the intervention

Method of measurement

Sonography

7

Description

Apgar score

Timepoint

Delivery time

Method of measurement

Clinical observation

8

Description

Newborn's bilirubin

Timepoint

Delivery time

Method of measurement

Enzymatic kit

9

Description

Newborns' hospitalization

Timepoint

After delivery

Method of measurement

Medical record

10

Description

Maternal pre-eclampsia

Timepoint

After delivery

Method of measurement

Medical record

Intervention groups

1

Description

Intervention group: Combined 2000 mg omega-3 fatty acids daily (Zahravi, Tabriz, Iran) and 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 6 weeks orally.

Category

Treatment - Drugs

2

Description

Intervention group: 2000 mg omega-3 fatty acids daily (Zahravi, Tabriz, Iran), for 6 weeks orally.

Category

Treatment - Drugs

3

Description

Intervention group: 5000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 6 weeks orally.

Category

Treatment - Drugs

4

Description

Control group: Omega-3 placebo daily (Zahravi, Tabriz,

Iran) and vitamin D placebo every 2 weeks (Zahravi, Tabriz, Iran), for 6 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Clinic

Full name of responsible person

Maryamalsadat Razavi

Street address

Pasdaran Avenue, Ardabil

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5613974156

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+98 45 3324 8888

Email

alavi@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ardabil University of Medical Sciences

Full name of responsible person

Sharam Habibzadeh

Street address

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Ardabil

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56189-85991

Phone

+98 45 3353 4776

Email

research@arums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Ardabil 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

Ghotbe Ravandi Boulevard, Kashan

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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