

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Clinical trial of the effect of combined omega-3 fatty acids and vitamin D supplementation compared with the placebo on metabolic profiles 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 such as markers of insulin metabolism and lipid profiles in patients with gestational diabetes.

Design

Parallel group, double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct

Population and sample size: 140 eligible patients with GDM among pregnant women, referred to Kosar Gynecology Clinic affiliated to Arak University of Medical Sciences, Arak, Iran will be selected to participate in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with gestational diabetes in the age range of 18 to 40 years old. Exclusion criteria: taking vitamin D and/or omega-3 fatty acids supplements, taking insulin, placenta abruption, preeclampsia, eclampsia, hypo and hyperthyroidism, smokers, kidney or liver diseases.

Intervention groups

Control group: Placebo (Zahravi, Tabriz, Iran), for 6 weeks orally. Intervention group 1: Combined 1000 mg omega-3 fatty acids twice a day (Zahravi, Tabriz, Iran) and 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 6 weeks orally. Intervention group 2: 1000 mg omega-3 fatty acids (Zahravi, Tabriz, Iran), twice a day, for 6 weeks orally. Intervention group 3: 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 6 weeks orally.

Main outcome variables

Markers of insulin metabolism (primary outcomes); lipid profiles

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: **IRCT201605135623N78**

Registration date: **2016-05-21, 1395/03/01**

Registration timing: **retrospective**

Last update: **2019-11-08, 1398/08/17**

Update count: **1**

Registration date

2016-05-21, 1395/03/01

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

2016-03-06, 1394/12/16

Expected recruitment end date

2016-05-05, 1395/02/16

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 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 in the age range of 18 to 40 years

Exclusion criteria:

Taking vitamin D and/or omega-3 fatty acids supplements
Taking insulin
Placenta abruption
Preeclampsia
Eclampsia
Hypo and hyperthyroidism
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: **140**

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 Clinic who is not involved in the trial and not aware of random sequences will allocate the numbered bottles of capsules to participants. Supplements and placebo are in the same packaging at the pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak

City

Arak

Province

Isfahan

Postal code

3814113634

Approval date

2016-03-05, 1394/12/15

Ethics committee reference number

IR.ARAKMU.REC.1394.373

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**

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

2**Description**

Insulin

Timepoint

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

Method of measurement

ELISA test

Secondary outcomes

1

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

HDL-cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

LDL

Timepoint

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

Method of measurement

Enzymatic kit

5

Description

VLDL

Timepoint

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

Method of measurement

Enzymatic kit

6

Description

FPG

Timepoint

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

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Control group: Placebo (Zahravi, Tabriz, Iran), for 6 weeks orally.

Category

Treatment - Drugs

2

Description

Intervention group 1: Combined 1000 mg omega-3 fatty acids twice a day (Zahravi, Tabriz, Iran) and 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 6 weeks orally.

Category

Treatment - Drugs

3

Description

Intervention group 2: 1000 mg omega-3 fatty acids (Zahravi, Tabriz, Iran), twice a day, for 6 weeks orally.

Category

Treatment - Drugs

4

Description

Intervention group 3: 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 6 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar outpatient 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?**

Yes

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

Associate professor

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