Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Country

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
Isfehan
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
Street address
Emam Khomeyni Avenue, Arak
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3814113634
Phone
+98 86 3223 3823
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jamilian.mehri@gmail.com

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

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

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Markazi

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3814113634

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research@aums.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, 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