

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of omega-3 supplementation on insulin resistance and lipid profiles in women with gestational diabetes

Protocol summary

Study aim

The aim of this study is to determine the effects of omega-3 supplementation on insulin resistance and lipid profiles in gestational diabetes.

Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers.

Settings and conduct

Among patients with GDM referred to Naghavi outpatient Clinic affiliated to Kashan University of Medical Sciences and Kosar outpatient Clinic affiliated to Arak University of Medical Sciences, 56 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 6 weeks after the intervention. At the beginning and the end of the intervention: 6 weeks.

Participants/Inclusion and exclusion criteria

Inclusion and Exclusion Criteria: Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation will be included in this study. The use of substitute treatments including hormone or vitamin supplements as well as those with pre-eclampsia, complete bed rest (CBR), intra uterine fetal death (IUFD), placenta abruption and preterm delivery will be excluded in the study.

Intervention groups

Intervention: Patients will be assigned to receive omega-3 supplement (n=28) and placebo (n=28).

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles (secondary outcomes) will be quantified at study baseline and end-of-trial

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201312265623N16**

Registration date: **2014-03-10, 1392/12/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-11, 1398/05/20**

Update count: **1**

Registration date

2014-03-10, 1392/12/19

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

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-03-03, 1392/12/12

Expected recruitment end date

2014-03-15, 1392/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 supplementation on insulin resistance and lipid profiles in women with gestational diabetes

Public title

The effect of omega-3 in the treatment of gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women aged 18-40 years Diagnosed with GDM at 24-28 weeks' gestation

Exclusion criteria:

The use of substitute treatments including hormone or vitamin supplements Patients with pre-eclampsia Complete bed rest (CBR) Intra uterine fetal death (IUFD) Placenta abruption Preterm delivery

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly allocated into two groups to take either supplements or placebo. 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.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Bolvare Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Approval date

2014-03-03, 1392/12/12

Ethics committee reference number

29/5/1/5007/P

Health conditions studied

1

Description of health condition studied

Gestational diabetes mellitus

ICD-10 code

O24.9

ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description

Insulin

Timepoint

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

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

Secondary outcomes

1

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

HDL-cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: Magnesium tablet, 250 mg, daily for 6 weeks orally.

Category

Treatment - Drugs

2

Description

Intervention group: Omega-3 pearl, daily for 6 weeks orally.

Category

Treatment - Drugs

3

Description

Control group: Placebo tablet for magnesium, daily for 6 weeks orally.

Category

Placebo

4

Description

Control group: Placebo pearl for omega-3, daily for 6 weeks orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi Clinic

Full name of responsible person

Zatollah Asemi

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Shahid Rajaei Avenue, Kashan

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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

Kashan University of Medical Sciences

Full name of responsible person

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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

Kashan 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

0098 36 1446 3378
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Person responsible for updating data

Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for scientific inquiries

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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