

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of omega-3 supplementation on inflammatory factors, biomarkers of oxidative stress and pregnancy outcomes in gestational diabetes

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of omega-3 supplementation on inflammatory factors, biomarkers of oxidative stress and pregnancy outcomes in gestational diabetes.

Design

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

Settings and conduct

Population and sample size: Among patients with gestational diabetes referred to Kosar Clinic affiliated to Arak University of Medical Sciences, 54 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Pregnant women aged 18-40 years diagnosed with GDM at 24-28 weeks' gestation.

Exclusion Criteria: Pre-existing diabetes, required complex diets, chronic medical conditions, significant psychiatric disease, smokers, kidney or liver diseases, chronic hypertension, hypothyroidism.

Intervention groups

Intervention group: Omega-3 pearl, 1000 mg, daily, for 6 weeks orally. Control group: Placebo pearl, daily, for 6 weeks orally.

Main outcome variables

Outcomes: Pregnancy outcomes (primary outcomes), hs-CRP, total nitrite and biomarkers of oxidative stress (secondary outcome) will be quantified at study baseline and end-of-trial.

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: **IRCT201406305623N20**
Registration date: **2014-07-16, 1393/04/25**
Registration timing: **retrospective**

Last update: **2019-10-25, 1398/08/03**

Update count: **1**

Registration date

2014-07-16, 1393/04/25

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

Arak University of Medical Science

Expected recruitment start date

2014-05-10, 1393/02/20

Expected recruitment end date

2014-05-28, 1393/03/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of omega-3 supplementation on inflammatory

factors, biomarkers of oxidative stress and 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 weeks' gestation

Exclusion criteria:

Pre-existing diabetes
Required complex diets
Chronic medical conditions
Significant psychiatric disease
Smokers
Kidney or liver diseases
Chronic hypertension
Hypothyroidism

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: **54**

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

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**

Arak University of Medical Sciences

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3814113634

Approval date

2014-05-09, 1393/02/19

Ethics committee reference number

93-165-20

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**

Infants' weight

Timepoint

Delivery time

Method of measurement

Scale

2**Description**

Infants' head circumference

Timepoint

Delivery time

Method of measurement

Tape

3**Description**

Newborns' length

Timepoint

Delivery time

Method of measurement

Tape

4**Description**

Polyhydramnios

Timepoint

After the intervention

Method of measurement

Sonography

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

Secondary 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

3

Description

Total antioxidant

Timepoint

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

Method of measurement

Spectrophotometry

4

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

5

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: Omega-3 pearl, 1000 mg, 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

Kossar Clinic

Full name of responsible person

Mehri Jamilian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak 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

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