Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of combined omega-3 and vitamin E supplementation on metabolic profiles in gestational diabetes

Protocol summary

Study aim

Objective: The aim of the current study is to evaluate the effects of combined omega-3 and vitamin E supplementation on metabolic profiles in gestational diabetes.

Design

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

Settings and conduct

Population and sample size: 60 patients with gestational diabetes of eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged 18-40 years old diagnosed with GDM at 24-28 weeks' gestation.
Exclusion criteria: Patients with premature preterm rupture of membrane, placenta abruption, pre-eclampsia, eclampsia, hypo and hyperthyroidism, urinary tract infection, smokers, kidney or liver diseases, required commencing insulin therapy during intervention

Intervention groups

Intervention group: Combined omega-3 and vitamin E pearl, 1000 mg omega-3 and 400 IU vitamin E, daily, for 6 weeks orally. Control group: Placebo pearl, daily, for 6 weeks orally.

Main outcome variables

Outcomes: Glucose homoeostasis parameters (primary outcomes) and lipid profiles (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: **IRCT201506085623N43**
Registration date: **2015-06-23, 1394/04/02**
Registration timing: **retrospective**

Last update: **2019-10-19, 1398/07/27**
Update count: **1**

Registration date

2015-06-23, 1394/04/02

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 36 1534 3570

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asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Science

Expected recruitment start date

2015-05-31, 1394/03/10

Expected recruitment end date

2015-06-14, 1394/03/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of combined omega-3 and vitamin E supplementation on metabolic profiles 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 old diagnosed with GDM at 24-28 weeks' gestation
Exclusion criteria:
Patients with premature preterm rupture of membrane Placenta abruption Pre-eclampsia Eclampsia Hypo and hyperthyroidism Urinary tract infection Smokers Kidney or liver diseases Required commencing insulin therapy during intervention
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: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
At study baseline, after balanced blocked randomisation, subjects will be allocated into two groups to take supplements (n=30) or the standard diet (n=30). 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 Science
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Approval date
2015-05-31, 1394/03/10
Ethics committee reference number
9434

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
Fasting plasma glucose
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic

2

Description
Insulin
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Elisa

3

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

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
VLDL
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
LDL
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Intervention group: Combined omega-3 and vitamin E pearl, 1000 mg omega-3 and 400 IU vitamin E, daily, for 6 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo pearl, 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
Street address
Shahid Rajaee Avenue, Kashan
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asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Science
Full name of responsible person
Gholamali Hamidi
Street address
Ghotbe Ravandi Boulevard, Kashan
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research@kaums.ac.ir
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 Science
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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Person responsible for scientific inquiries

Contact

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Position
PhD of Nutrition
Latest degree
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Person responsible for updating data

Contact

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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