Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Clinical trial of the effect of combined vitamin D and evening primrose oil supplementation on metabolic profiles in gestational diabetes

Protocol summary

Study aim
The aim of the current study is to evaluate the effects of combined vitamin D and evening primrose oil supplementation on metabolic profiles in gestational diabetes.

Design
Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct
Population and sample size: 60 patients with GDM among pregnant women of eligible and referred to Gynecology Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: In the current study, pregnant women aged 18-40 years with gestational diabetes (GDM) at weeks 24-28 of gestation will be included. Exclusion criteria: Pre-eclampsia, eclampsia, hypo- and hyperthyroidism, urinary tract infection, smokers, kidney or liver diseases and those requiring commencement of insulin therapy during treatment.

Intervention groups
Intervention: Patients will be assigned to receive either combined vitamin D and evening primrose oil supplements (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables
Outcomes: Markers of insulin resistance (primary outcomes) and lipid profiles (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201509115623N52**
Registration date: **2015-09-16, 1394/06/25**
Registration timing: **registered_while_recruiting**
Last update: **2019-09-22, 1398/06/31**
Update count: **1**

Registration date
2015-09-16, 1394/06/25

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 Sciences

Expected recruitment start date
2015-09-02, 1394/06/11

Expected recruitment end date
2015-09-18, 1394/06/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of combined vitamin D and evening primrose oil 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 Diagnosed with GDM at weeks 24-28 of gestation

Exclusion criteria:

Pre-eclampsia Eclampsia hypo- and hyperthyroidism Urinary tract infection Smokers Kidney or liver diseases Those requiring commencement of insulin therapy during treatment.

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

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

Ethics committee of Arak University of Medical Sciences

Street address

Vice-chancellor for Education and Research, Sardasht Avenue, Arak

City

Arak

Province

Markazi

Postal code

3814113634

Approval date

2015-09-01, 1394/06/10

Ethics committee reference number

IR.ARAKMU.REC.1394.161

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

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

Questionnaire

Secondary outcomes

1

Description

Fasting blood sugar

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

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

HDL-cholesterol

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

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 vitamin D and evening primrose oil pearl, 1000 IU vitamin D plus 1000 mg evening primrose oil, 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

Gynecology Clinic

Full name of responsible person

Mehri Jamilian

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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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rafiee-m@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
PhD of Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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