

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Alpha-lipoic acid supplementation effects on the lipid profile, antioxidant capacity and malondialdehyde in patients with gestational diabetes mellitus

Protocol summary

Study aim

The aim of this study is to determine the effects of alpha-lipoic acid (ALA) supplementation on serum some biochemical variables in women with gestational diabetes mellitus (GDM).

Design

In this double blind study, a total number of 60 women with GDM will be selected. They will be divided into two groups of intervention (ALA) and control (placebo) by simple randomization method. They will be matched in age and BMI.

Settings and conduct

The aim and procedures of the study will be conveyed to the participants and written informed consent will be obtained from each of them. Patients were not aware of the type of drug and the statistician was not aware of the type of groups.

Participants/Inclusion and exclusion criteria

Major inclusion criteria are no history of GDM and not consumption of vitamin and mineral supplements during the last 6 months. Major Exclusion criteria are preterm delivery, preeclampsia, the need for insulin or oral medication for lowering blood sugar during the intervention and bed rest.

Intervention groups

Supplement group will receive ALA (one 100 mg capsule for 8 weeks) and the control group will receive placebo capsule containing cellulose acetate with the same dosage and period.

Main outcome variables

Serum levels of glucose, hemoglobin A1c, insulin, lipid profile, antioxidant capacity and malodialdehyde.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012925949N4**

Registration date: **2017-02-02, 1395/11/14**

Registration timing: **prospective**

Last update: **2018-08-27, 1397/06/05**

Update count: **1**

Registration date

2017-02-02, 1395/11/14

Registrant information

Name

Ali Khosrowbeygi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3638

Email address

a.khosrowbeygi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Arak University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Alpha-lipoic acid supplementation effects on the lipid profile, antioxidant capacity and malondialdehyde in patients with gestational diabetes mellitus

Public title

Effects of alpha-lipoic acid supplementation in gestational diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No history of gestational diabetes mellitus Not consumption of vitamin and mineral supplements during the last 6 months

Exclusion criteria:

Preeclampsia Insulin therapy Oral glucose lowering drugs consumption Bed rest Alcoholism smoking

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method using table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, healthcare providers and outcome assessors are blinded.

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

Sardasht, Basij sq, Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2017-01-02, 1395/10/13

Ethics committee reference number

IR.ARAKMU.REC.1395.343

Health conditions studied

1

Description of health condition studied

Gestational diabetes mellitus

ICD-10 code

O24.4

ICD-10 code description

Diabetes mellitus arising in pregnancy

Primary outcomes

1

Description

Fasting glucose

Timepoint

Before and after 8 weeks of intervention

Method of measurement

Colorimetric

2

Description

Fasting insulin

Timepoint

Before and after 8 weeks of intervention

Method of measurement

ELISA

3

Description

HbA1C

Timepoint

Before and after 8 weeks of intervention

Method of measurement

Chromatography

4

Description

HDL-C

Timepoint

Before and after 8 weeks of intervention

Method of measurement

Spectrophotometric

5

Description

LDL-C

Timepoint

Before and after 8 weeks of intervention

Method of measurement

Friedewald's equation

6

Description

TG

Timepoint

Before and after 8 weeks of intervention

Method of measurement

Colorimetric

7

Description

TC

Timepoint

Before and after 8 weeks of intervention

Method of measurement

Colorimetric

8

Description

Malondialdehyde

Timepoint

Before and after 8 weeks of intervention

Method of measurement

Colorimetric

9

Description

Antioxidant capacity

Timepoint

Before and after 8 weeks of intervention

Method of measurement

Colorimetric

Secondary outcomes

1

Description

BMI

Timepoint

Before and after 8 weeks of intervention

Method of measurement

Formula

Intervention groups

1

Description

Intervention group: One capsule alpha-lipoic acid (100 mg) per day for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: One capsule placebo cellulose acetate (100 mg) per day for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Mehri Jamilian

Street address

Imam Khomeini Ave., Next to the gas company, Taleghani hospital, Arak

City

Arak

Province

Markazi

Postal code

3816149369

Phone

+98 86 3277 6063

Email

mjamilian@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

Street address

Basij Square, Sardasht, Arak University of Medical Sciences, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3638

Email

Research@arakmu.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 of 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

Sciences, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3501

Fax**Email**

a.khosrowbeygi@arakmu.ac.ir

Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Ali Khosrowbeygi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Basij Square, Sardasht, Department of Biochemistry,
School of Medicine, Arak University of Medical
Sciences, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3501

Fax**Email**

a.khosrowbeygi@arakmu.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Ali Khosrowbeygi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Basij Square, Sardasht, Department of Biochemistry,
School of Medicine, Arak University of Medical
Sciences, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3501

Fax

+98 86 3417 3529

Email

a.khosrowbeygi@arakmu.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Ali Khosrowbeygi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Basij Square, Sardasht, Department of Biochemistry,
School of Medicine, Arak University of Medical

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only results of main outcomes.

When the data will become available and for how long

Six months after publishing of the results.

To whom data/document is available

Only for academic staffs and universities researches.

Under which criteria data/document could be used

Only for international and between universities researches.

From where data/document is obtainable

Ali Khosrowbeygi a.khosrowbeygi@arakmu.ac.ir

What processes are involved for a request to access data/document

1. Requesting a team work clinical trial via email.
2. Approving the proposal.
3. Registration of the trial.

Comments

No comments