

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effects of alpha-lipoic acid supplementation on serum levels of leptin, adiponectin and their ratio in women with gestational diabetes

Protocol summary

Summary

Objectives: The aim of this study is to determine the effects of alpha-lipoic acid (ALA) supplementation on serum levels of leptin, adiponectin 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 random sampling. They will be matched in age and BMI. The endocrinologist, pharmacy and the participants will be blinded to the study interventions. **Setting 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. **Major 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:** One group will receive ALA (one 100 mg capsule for 8 weeks) and the other group will receive placebo capsule containing cellulose acetate with the same dosage and period. **Main outcome measures (variables):** Serum levels of leptin, adiponectin and the adiponectin-to-leptin ratio will be evaluated at the beginning and at the end of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091225949N5**
Registration date: **2017-09-22, 1396/06/31**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-22, 1396/06/31

Registrant information

Name

Ali Khosrowbeygi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Arak University of Medical Sciences

Expected recruitment start date

2017-09-13, 1396/06/22

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

Effects of alpha-lipoic acid supplementation on serum levels of leptin, adiponectin and their ratio in women with gestational diabetes

Public title

Effects of alpha-lipoic acid supplementation in women with gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: No history of GDM and not consumption of vitamin and mineral supplements during the last 6 months. Exclusion criteria: Preterm delivery; preeclampsia; the need for insulin or oral medication for lowering blood sugar during the intervention; bed rest; alcoholism and smoking.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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 square, Arak University of Medical Sciences

City

Arak

Postal code

Approval date

2017-08-14, 1396/05/23

Ethics committee reference number

IR.ARAKMU.REC.1396.91

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

Fasting leptin

Timepoint

Before and after 8 weeks of intervention

Method of measurement

ELISA

4

Description

Fasting adiponectin

Timepoint

Before and after 8 weeks of intervention

Method of measurement

ELISA

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

Hadiseh Asl Fallah

Street address

Shora Square, Imam Khomeini Street, Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Arak University of Medical Sciences

Full name of responsible person

Dr. Ali Ghazavi

Street address

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

City

Arak

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Ali Khosrowbeygi

Position

PhD

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty