Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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
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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