

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Alpha-lipoic acid supplementation effects on serum values of catalase, thiol groups, oxidative stress index and homeostasis model assessment of beta-cell function (HOMA-B) in women with gestational diabetes

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 (daily 300 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

on serum values of catalase, thiol groups, oxidative stress index and homeostasis model assessment of beta-cell function (HOMA-B)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181113041639N1**

Registration date: **2019-05-25, 1398/03/04**

Registration timing: **prospective**

Last update: **2019-08-26, 1398/06/04**

Update count: **1**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Masoome Mandani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 9249

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-31, 1398/06/09

Expected recruitment end date

2020-02-29, 1398/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Alpha-lipoic acid supplementation effects on serum

values of catalase, thiol groups, oxidative stress index and homeostasis model assessment of beta-cell function (HOMA-B) in women with gestational diabetes

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 From 18 years old to 40 years old No smoking
Exclusion criteria:
 consumption of vitamin and mineral supplements during the last 6 months Preterm delivery Unwillingness to cooperate Preeclampsia and other complications pregnancy during intervention Thyroid disorders Thalassemia Severe anemia Autoimmune diseases Digestive diseases Insulin therapy Oral glucose lowering drugs consumption Bed rest

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
Participants, healthcare providers and outcome assessors are blinded.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, healthcare providers and outcome assessors are blinded. The drug and placebo are packaged in similar packages. The treatment group and placebo group will not be aware of the type of intervention they receive. The statistician will not be informed about the grouping done.

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
 Arak University of Medical Sciences, Basij square, Sardasht, Arak
City
 Arak
Province
 Markazi
Postal code
 3848176941
Approval date
 2019-03-07, 1397/12/16
Ethics committee reference number
 IR.ARAKMU.REC.1397.242

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
 Antioxidant capacity
Timepoint
 Before and after 8 weeks of intervention
Method of measurement
 Colorimetric

3

Description
 Total oxidant status
Timepoint
 Before and after 8 weeks of intervention
Method of measurement
 کالریمتری

4

Description

Stress oxidative index
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Formula

5

Description
Glutathione
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Spectrophotometric

6

Description
BMI
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Formula

7

Description
Catalas
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Spectrophotometric

8

Description
insulin
Timepoint
Before and after 8 weeks of intervention
Method of measurement
ELISA

9

Description
Malondialdehyde
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Colorimetric

10

Description
HOMA-B
Timepoint
Before and after 8 weeks of intervention
Method of measurement
formula

Secondary outcomes

1

Description
BMI
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Formula

Intervention groups

1

Description
Intervention group: Intervention group: One capsule alpha-lipoic acid (300 mg) per day for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Control group: One capsule placebo cellulose acetate (300 mg) day for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali hospital
Full name of responsible person
Bita Badenoosh
Street address
Kamali hospital, Kamali street, Shohada square, Shahid Beheshti street, Karaj
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Alborz
Postal code
3134877179
Phone
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b_badehnoosh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad Arjomandzadegan
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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
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
Arak University of Medical Sciences

Full name of responsible person
Masoome Mamdani

Position
student

Latest degree
Master

Other areas of specialty/work
Biochemistry

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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