

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Effects of Alpha-lipoic acid supplementation on the Liver and kidney function tests 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 the Liver and kidney function tests 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.

##### Settings and conduct

The endocrinologist and the participants will be blinded to the study interventions. The aim and procedures of the study will be conveyed to the participants and written informed consent will be obtained from each of them.

##### Participants/Inclusion and exclusion criteria

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 groups

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 variables

Serum levels of gamma-glutamyltransferase (GGT), alanine transaminase (ALT), aspartate transaminase (AST), alkaline phosphatase (ALP), urea and creatinine will be evaluated at the beginning and at the end of the intervention.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160111025949N6**

Registration date: **2018-01-02, 1396/10/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-02, 1396/10/12**

Update count: **0**

##### Registration date

2018-01-02, 1396/10/12

##### 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

##### Expected recruitment start date

2017-12-30, 1396/10/09

##### Expected recruitment end date

2018-02-24, 1396/12/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Effects of Alpha-lipoic acid supplementation on the Liver and kidney function tests 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 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 Smoking

**Age**

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

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple random sampling using random number table.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The endocrinologist and the participants will be blinded to the study interventions.

**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

**Province**

Markazi

**Postal code**

3848176941

**Approval date**

2017-12-03, 1396/09/12

**Ethics committee reference number**

IR.ARAKMU.REC.1396.216

**Health conditions studied****1****Description of health condition studied**

Gestational diabetes mellitus

**ICD-10 code**

O24.4

**ICD-10 code description**

Gestational diabetes mellitus

**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**

Gamma-glutamyltransferase

**Timepoint**

Before and after 8 weeks of intervention

**Method of measurement**

Colorimetric

**5****Description**

Alanine transaminase

**Timepoint**

Before and after 8 weeks of intervention

**Method of measurement**

Colorimetric

**6**

**Description**

Aspartate transaminase

**Timepoint**

Before and after 8 weeks of intervention

**Method of measurement**

Colorimetric

**7**

**Description**

Alkaline phosphatase

**Timepoint**

Before and after 8 weeks of intervention

**Method of measurement**

Colorimetric

**8**

**Description**

Urea

**Timepoint**

Before and after 8 weeks of intervention

**Method of measurement**

Colorimetric

**9**

**Description**

Creatinine

**Timepoint**

Before and after 8 weeks of intervention

**Method of measurement**

Colorimetric

**Secondary outcomes**

**1**

**Description**

Body mass index

**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**

Ali Khosrowbeygi

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Imam Khomeini Avenue

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Muhammad Arjmandzadegan

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Basij Square, Sardasht, Arak University of Medical Sciences

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**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**  
Ali Khosrowbeygi  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Biochemistry  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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;  
khosrowbeygi@yahoo.com

### 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**