# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

04 Aug 2026

## Investigate the effect of alpha lipoic acid supplementation on serum level of LP-PLA2, it`s distribution between HDL and apo B containing lipoproteins and related oxidative stress and inflammatory markers in type 2 diabetic patients

## Protocol summary

**Study aim**
Determination of the effect of alpha lipoic acid supplementation on serum level of lipoprotein-dependent phospholipase A2 and related inflammatory and oxidative stress markers in type 2 diabetic patients

**Design**
A Randomized, Placebo-Controlled, Double-Blind, Parallel-Group, Clinical trial

**Settings and conduct**
Patients with type 2 diabetes who come to the Diabetes Clinic of Tehran University of Medical Sciences who have inclusion criteria will be included in the study. These patients will be randomized into two intervention and control groups for 2 months. The supplement and placebo are named by a third person in two forms A and B, and the researcher, analyst, and participants will be unaware of this categorization.

**Participants/Inclusion and exclusion criteria**
Inclusion Criteria: Willingness to cooperate; Age between 40-60 years old; Body mass index (BMI) between 18.5 to 29.9; At least 2 years of diagnosed type 2 diabetes; Controlled Diabetes (HbA1C <7%). Non-inclusion criteria: Taking Insulin; History of angina, myocardial infarction, and stroke, as well as other chronic diseases and infectious diseases in the past year; Tobacco and alcohol consumption in the last three months; Changes in treatment protocols in the last three months; taking any medicine other than metformin, glibenclamide, statin drugs, ACEI, ARB and doses less than 80 mg aspirin; Regular use of herbal Supplements containing antioxidants and omega-3 in the last three months (at least once a week); Pregnancy and lactation

**Intervention groups**
Patients in the intervention group received 1200 mg of alpha-lipoic acid supplement per day, and in the control group received placebo capsules (maltodextrin) for 2 months.

**Main outcome variables**
Lp-PLA2 and its lipoprotein distribution, ICAM-1, VCAM-1, TNF-a, IL-6, 8-isoproprane, and OX-LDL and APO A1

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180407039219N1**
Registration date: **2018-04-27, 1397/02/07**
Registration timing: **prospective**

Last update: **2018-04-27, 1397/02/07**
Update count: **0**

**Registration date**
2018-04-27, 1397/02/07

**Registrant information**

**Name**
Nima Baziar

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-05-05, 1397/02/15

**Expected recruitment end date**

2018-11-06, 1397/08/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigate the effect of alpha lipoic acid supplementation on serum level of LP-PLA2, it`s distribution between HDL and apo B containing lipoproteins and related oxidative stress and inflammatory markers in type 2 diabetic patients

**Public title**

Investigating the effect of alpha lipoic acid supplementation on oxidative stress and inflammatory markers in type 2 diabetic patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Willingness to cooperate Age between 40-60 years old Body mass index (BMI) between 18.5 to 29.9 At least 2 years of diagnosed type 2 diabetes Controlled diabetes (HbA1C < 7%)

**Exclusion criteria:**

Taking insulin History of angina, myocardial infarction, and stroke, as well as other chronic diseases including liver disease, gastrointestinal disease, kidney disease, malignant disease, thyroid disease and other chronic and infectious diseases in the past year Tobacco and alcohol consumption in the last three months Changes in treatment protocols in the last three months Taking any medicine other than metformin, glibenclamide, statin drugs, ACEI, ARB and doses less than 80 mg aspirin Regular use of herbal Supplements containing antioxidants and omega-3 in the last three months (at least once a week) Pregnancy and lactation

**Age**

From **40 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, diabetic patients will be randomly (block randomization) assigned to two intervention and control groups based on sex and menopausal (stratified randomization). We will create four blocks of letters T (treatment) and C (control), such that half the letters of each block T and the other half C (eg TTCC, CTTC, etc.). The blocks will be created and numbered then we will randomly select the blocks needed to reach the sample size and we will put them together. Based on the created pattern, patients will be assigned to two intervention and control groups

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The supplements and placebos are similar in terms of shape, odor, taste, and packaging, and are labeled by a third person (from experts in the diabetes clinic) in two forms A and B.Patients, researcher and analyst would not know who was receiving the supplements and who was receiving a placebo.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Qods st., Keshavarz blv.

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Tehran

**Province**

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**Postal code**

1417653761

**Approval date**

2018-02-20, 1396/12/01

**Ethics committee reference number**

IR.TUMS.VCR.REC.1396.4583

## Health conditions studied

**1**

**Description of health condition studied**

Type 2 diabetes mellitus

**ICD-10 code**

E11

**ICD-10 code description**

Type 2 diabetes mellitus

## Primary outcomes

**1**

**Description**

Lipoprotein-associated phospholipase A2 (Lp-PLA2)

**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
ELISA assay

**2**

**Description**
Lipoprotein-associated phospholipase A2 distribution among lipoproteins
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
ELISA assay

**3**

**Description**
ICAM-1
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
ELISA assay

**4**

**Description**
VCAM-1
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
ELISA assay

**5**

**Description**
TNF-a
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
ELISA assay

**6**

**Description**
Interleukin 6
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
ELISA assay

**7**

**Description**
8-Isoprostane
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
ELISA assay

**8**

**Description**
OX-LDL
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
ELISA assay

**9**

**Description**
Apolipoprotein A1
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
ELISA assay

## Secondary outcomes

**1**

**Description**
Glucose
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
Photometric assay

**2**

**Description**
Insuline
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
ELISA assay

**3**

**Description**
Total cholesterol
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
enzymatic assay

**4**

**Description**
HDL Cholesterol
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
enzymatic assay

**5**

**Description**
LDL Cholesterol
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
Friedewald formula

**6**

**Description**
Triglyceride
**Timepoint**
Baseline and 8 weeks after intervention
**Method of measurement**
enzymatic assay

## Intervention groups

**1**

**Description**
Intervention group: The patients in the intervention group will receive 1200 mg daily of alpha-lipoic acid supplements in the form of two 600 mg capsules and they will be asked to take capsules every 12 hours 30 minutes before breakfast and dinner for 2 months. Supplements will be provided by Karen critical pharmaceutical and nutritional supplements company.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: The patients in the control group will receive two placebo capsules (maltodextrin) and they will be asked to take capsules every 12 hours 30 minutes before breakfast and dinner for 2 months.Placebo capsules will be provided by Karen critical pharmaceutical and nutritional supplements company.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Diabetes & Metabolic Diseases Clinic of Tehran University of Medical Sciences
**Full name of responsible person**
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## Sponsors / Funding sources

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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**
Tehran 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**
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Tehran University of Medical Sciences
**Full name of responsible person**
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**Other areas of specialty/work**
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Not applicable

**Data Dictionary**
Not applicable