

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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-isoproprene, 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5975

Email address

n-baziar@razi.tums.ac.ir

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.

City

Tehran

Province

Tehran

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- α

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

Nima Baziar

Street address

Next to the Emergency of Heart Center, Shahrivar St.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Saeed Hosseini

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

School of Nutritional Sciences & Dietetics, Tehran
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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

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Full name of responsible person

Nima Baziar

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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