Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 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

Country
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.

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-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
Nima Baziar
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Sponsors / Funding sources

1

Sponsor
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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
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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