

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the effect of Atorvastatin alone & in combination with vitamin E on peroxisome proliferator-activated receptor-gamma gene expression and insulin resistance indices in type 2 diabetic patients with hyperlipidemia

Protocol summary

Study aim

Determination the effect of atorvastatin alone and in combination with vitamin E on Peroxisome Proliferator-Activated Receptor-gamma gene expression in type 2 diabetic patients with hyperlipidemia Determination the effect of atorvastatin alone and in combination with vitamin E on insulin resistance indice (HOMA-IR) in type 2 diabetic patients with hyperlipidemia Determination the effect of atorvastatin alone and in combination with vitamin E on fasting serum insulin in type 2 diabetic patients with hyperlipidemia Determination the effect of atorvastatin alone and in combination with vitamin E on fasting blood glucose in type 2 diabetic patients with hyperlipidemia Determination the effect of atorvastatin alone and in combination with vitamin E on blood lipid profile (triglyceride, total cholesterol, LDL and HDL) in type 2 diabetic patients with hyperlipidemia Determination the effect of atorvastatin alone and in combination with vitamin E on weight loss in type 2 diabetic patients with hyperlipidemia Determination the effect of atorvastatin alone and in combination with vitamin E on waist circumference in type 2 diabetic patients with hyperlipidemia

Design

In this research, 30 eligible type 2 diabetic patients with hyperlipidemia referring to clinics of Vali-e-Asr Hospital were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

This study is a double-blinded (researcher/patient) randomized clinical trial. the aim of the present study is finding the suitable treatment method with lower complications for type 2 diabetic patients with hyperlipidemia. Thirty women with type 2 diabetes which have hyperlipidemia and HbA1c= 7-9% who were

attending to the clinics of Vali-e-Asr Hospital will be enrolled. Patients were randomly divided to two equal groups. The first group: receive atorvastatin 20 mg plus placebo and the second group receive 20 mg atorvastatin plus 400 IU vitamin E supplement daily for 12 weeks. At the end, results will be compared between the two groups, as well as in each group from baseline up to the end.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with type 2 diabetes who receive 20 mg per day atorvastatin to control blood lipid; body mass index between 25 to 35 kg/m²; age of 18 to 65 years; glycated hemoglobin of 7 to 9 percent; Exclusion criteria: body mass index lower than 25 kg/m²; pregnant and lactating women; patients with chronic diseases; intake of thiazolidinediones family; intake of supplements at least for 3 month ago; use of alcohol or cigarette; malabsorptive diseases; people on special diets

Intervention groups

Control group: 20 mg atorvastatin plus placebo, daily
Intervention group: 20 mg atorvastatin plus 400 IU vitamin E supplement, daily

Main outcome variables

amount of Peroxisome Proliferator-activated receptor-gamma gene expression Insulin resistance indice (HOMA-IR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170918036256N1**

Registration date: **2017-12-15, 1396/09/24**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-15, 1396/09/24**

Update count: **0**

Registration date

2017-12-15, 1396/09/24

Registrant information

Name

Banafsheh Sadat Tabaei Jabali

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 0300

Email address

tabaei.banafsheh@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2017-07-02, 1396/04/11

Expected recruitment end date

2018-01-10, 1396/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Atorvastatin alone & in combination with vitamin E on peroxisome proliferator-activated receptor-gamma gene expression and insulin resistance indices in type 2 diabetic patients with hyperlipidemia

Public title

Effect of Atorvastatin in combination with vitamin E on treatment of hyperlipidemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: atorvastatin intake at the dose of 20 mg/day; fasting blood sugar more than 126 mg/dl & two hour plasma glucose more than 200 mg/dl in two regular tests; body mass index between 25 to 35 kg/m²; age of 18 to 65 years; glycated hemoglobin of 7 to 9 percent; Iranian ethnicity Exclusion criteria: body mass index lower than 25 kg/m²; pregnant and lactating women or whom decide to pregnancy; chronic diseases such as inflammatory diseases, heart, liver, renal failure, cancer, acute myocardial infarction, type 1 diabetes, stroke & serious injuries; drugs of thiazolidinediones family such as pioglitazone; intake of multivitamin or antioxidant supplements at least for 3 month ago; use of alcohol or cigarette; malabsorptive diseases such as celiac & steatorrhea; liver genetic diseases such as copper or iron storage; athletes; people on special diets

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. By a flip of a coin, the first patient will be considered at the intervention and the second one will be as control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

After collecting the consent form to participate in the study, participants received drugs with the same shape and number. Clinical care person and researcher were blinded through coding at the random allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Sciences

Street address

12th street., Mahdavi Blvd., Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

zums.rec.1395.268

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Peroxisome proliferator-activated receptor-gamma gene expression

Timepoint

At the beginning and after 12 weeks

Method of measurement

Polymerase chain reaction

2

Description

Insulin resistance indice

Timepoint

At the beginning and after 12 weeks

Method of measurement

HOMA-IR formula

Secondary outcomes

1

Description

Triglyceride

Timepoint

At the beginning and after 12 weeks

Method of measurement

Autoanalyzer

2

Description

Total cholesterol

Timepoint

At the beginning and after 12 weeks

Method of measurement

Autoanalyzer

3

Description

Low density lipoprotein cholesterol

Timepoint

At the beginning and after 12 weeks

Method of measurement

Autoanalyzer

4

Description

High density lipoprotein cholesterol

Timepoint

At the beginning and after 12 weeks

Method of measurement

Autoanalyzer

5

Description

Fasting glucose

Timepoint

At the beginning and after 12 weeks

Method of measurement

Autoanalyzer

6

Description

Two-hour plasma glucose

Timepoint

At the beginning and after 12 weeks

Method of measurement

Autoanalyzer

7

Description

Insulin resistane

Timepoint

At the beginning and after 12 weeks

Method of measurement

Fasting insulin *fasting glucose/ 405

8

Description

Fasting insulin

Timepoint

At the beginning and after 12 weeks

Method of measurement

ELISA kit

9

Description

Weight reduction

Timepoint

At the beginning and after 12 weeks

Method of measurement

Scale

10

Description

Waist circumference

Timepoint

At the beginning and after 12 weeks

Method of measurement

Meter

11

Description

Glycosylated hemoglobin

Timepoint

At the beginning and after 12 weeks

Method of measurement

Autoanalyzer

Intervention groups

1

Description

Atorvastatin 20 mg (Jalinus Co, Iran) and vitamin E 400 IU (Zahravi Co, Iran), daily after meal, for 12 weeks

Category

Treatment - Drugs

2

Description

Atorvastatin 20 mg (Jalinus Co, Iran) and placebo (containing corn oil, Zahravi Co, Iran), daily after meal, for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-e-Asr hospital

Full name of responsible person

Maryam Jameshorani

Street address

Vali-e-Asr Ave, Vali-e-Asr hospital

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 24 3344 0300

Email

dr.shirinjameshorani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Ali Mellati

Street address

12th St, Mahdavi Blv, Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 24 3344 0300

Email

mellati@zums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Banafsheh Sadat Tabaei Jabali

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Biochemistry

Street address

12th St, Mahdavi Blv, Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 24 3344 0300

Fax

Email

tabaei.banafsheh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Ali Mellati

Position

Professor
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
12th St, Mahdavi Blv, Zanzan University of Medical Sciences
City
Zanzan
Province
Zanzan
Postal code
4515613191
Phone
+98 24 3344 0300
Fax
Email
mellati@zums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Zanzan University of Medical Sciences
Full name of responsible person
Banafsheh Sadat Tabaei Jabali
Position
Master student of Clinical Biochemistry
Latest degree
Bachelor
Other areas of specialty/work
Biochemistry
Street address
12th St, Mahdavi Blv, Zanzan University of Medical Sciences
City
Zanzan
Province

Zanzan
Postal code
4515613191
Phone
+98 24 3344 0300
Fax
Email
tabaei.banafsheh@zums.ac.ir
Web page address

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Results of data analysis will be reported.

When the data will become available and for how long

access starts 6 month after publishing the results

To whom data/document is available

Researchers at the universities

Under which criteria data/document could be used

Useless

From where data/document is obtainable

E-mail tabaei.banafsheh@zums.ac.ir

What processes are involved for a request to access data/document

Electronic mail

Comments