Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 randomely devided to two equal groups. The first group: recieve atorvastatin 20 mg plus placebo and the second group recieve 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 critera: women with type 2 diabetes who recieve 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 tiazolidinediones 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

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Iran (Islamic Republic of)

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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 Atorvastation 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: bogy 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 tiazolidinediones 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 recieved drugs with the same shape and number. Clinical care person and researcher were blinded through coding at the randome 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Ali Mellati

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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

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

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Latest degree

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Other areas of specialty/work

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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