

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of combination therapy with Ezetimibe and Gemfibrozile on post-prandial hypertriglyceridemia in type 2 Diabetic patients

Protocol summary

Summary

90 subjects with DM 2, HbA1c <8% and the hyper fasting triglyceride (TG> 250 mg / dl) and without any endocrine disease will be selected and after a 14-hfasting , their blood samples will collected to measure total cholesterol , HDL, ApoA, ApoE, FBS, HbA1c, LFT (ALP, AST, ALT), Cr, TSH by a single laboratory. Then each patient will receive Fat load test standard calories contains 50 grams of fat and 650 kg cal (50 grams butter and 45 grams of animal pasteurized palm and 60 grams of lavash bread).Then the nurse of Diabetes Center will categorized subjects randomly. Group 1 will be treated by ezetimibe. 10 mg + gemfibrozil 1200mg, for 2th group, it will be gemfibrozil 1200mg and 3th group will be received 10mg ezetimibe+ 10mg atorvastatin. After completing 6 month period of treatment, subject will be undertaken 14-h fasting and mentioned process will be repeated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105311179N5**

Registration date: **2011-06-27, 1390/04/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-27, 1390/04/06

Registrant information

Name

Faranak Sharifi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 1727 0815

Email address

zmdrc@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Science

Expected recruitment start date

2011-01-20, 1389/10/30

Expected recruitment end date

2012-04-18, 1391/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combination therapy with Ezetimibe and Gemfibrozile on post-prandial hypertriglyceridemia in type 2 Diabetic patients

Public title

Combination therapy with Ezetimibe and Gemfibrozile on post-prandial hypertriglyceridemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The average age of 20-65-HbA1C <8%-hypertriglycemia>250mg/dlPatients with DM type 2

Exclusion criteria: Treating with antilipid agents, thyroid disease, acute or chronic liver disease, association with other endocrine disease like Acromegaly or cushing , renal dysfunction (GFR<60), Hypertriglyceridemia>1000 and LDL >190mg/dl

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

zanjan metabolic research center,zanjan university of medical science

Street address

Azadi Boulevard-Zanjan University Of Medical Sciences

City

zanjan

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

19/3-3/2112

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

lipid profile

Timepoint

6 weeks

Method of measurement

labratory

Secondary outcomes

1

Description

Apo protein B

Timepoint

6 weeks

Method of measurement

labratory

2

Description

apo protein A

Timepoint

6 weeks

Method of measurement

labratory

Intervention groups

1

Description

Group1:ezetimibe 10mg plus gemfibrozile 1200mg

Category

Treatment - Drugs

2

Description

Group 2:1200mg gemfibrozile

Category

Treatment - Drugs

3

Description

Group3: ezetimibe 10mg plus atorvastatin 10mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan Endocrine Clinic

Full name of responsible person

Dr.faranak. sharifi

Street address

Vali-asr hosopital, Sheikh fazollahe nouri avenue

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan Metabolic Research Center, Zanjan University of medical science

Full name of responsible person

Dr.alireza. biglari,

Street address

Azadi bulvar

City

Zanjan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zanjan Metabolic Research Center, Zanjan University of medical science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Zanjan Metabolic Diseases Research Center

Full name of responsible person

Dr.Faranak Sharifi

Position

full professor

Other areas of specialty/work**Street address**

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Fax**Email**

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Zanjan Metabolic Research Center

Full name of responsible person

Dr.nima hojehgani

Position

Internal disease resident

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact**Name of organization / entity**

Metabolic Disease Research Center

Full name of responsible person

Dr zahra shajari

Position

General physicien

Other areas of specialty/work**Street address**

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City

Zanjan

Postal code**Phone****Fax****Email****Web page address**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty