Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+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/dl,Patients 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
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Person responsible for scientific inquiries

Contact
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Dr.nima hojehgani
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Person responsible for updating data

Contact
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General physicien
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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