Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of therapeutic effects of Fenofibrate and Gemfibrozil on Lipid profile in patients withType 2 Diabetes Mellitus

Protocol summary

Summary

This study aimed to Comparison of therapeutic effects of Fenofibrate and Gemfibrozil on Lipid profile in patients withType 2 Diabetes Mellitus. sixty patients with type 2 diabetes with Inclusion criteria(LDL<100, TG>200, Non HDL chol >130) will be randomly divided in 2 groups including 30 patients in the group that will be receive Fenofibrate and 30 patients in othe rgroup will be receive Gemfibrozil. After3 , blood samples will be obtained.Lipid profil in each sample will be measured to camparison of therapeutic effects of Fenofibrate and Gemfibrozil on

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401096710N4**
Registration date: **2014-01-24, 1392/11/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-01-24, 1392/11/04

Registrant information

Name
Mitra Niafar
Name of organization / entity
Tabriz university of medical sciences
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Iran (Islamic Republic of)
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+98 41 1335 7850
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niafarm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research deputy of Tabriz University of Medical Sciences

Expected recruitment start date

2013-12-20, 1392/09/29

Expected recruitment end date

2014-12-20, 1393/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects of Fenofibrate and Gemfibrozil on Lipid profile in patients withType 2 Diabetes Mellitus

Public title

Comparison of therapeutic effects of Fenofibrate and Gemfibrozil on Lipid in patients with Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: type 2 diabetes ;LDL chol <100 mg/dl ,TG>200 mg/dl ; Non HDL chol >130 mg/dl. Exclusion criteria: age<18;hypothyroidisim;BMI >30,pregnancy;Lactation ;Liver failure ;Renal failure (GFR<30); HB A1C >8%.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences Ethics Committee
Street address
Faculty of Medicine- Daneshgah Ave. Tabriz
City
Tabriz
Postal code
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
5/4/7615

Health conditions studied

1

Description of health condition studied
Mixed hyperlipidaemia
ICD-10 code
E78.2
ICD-10 code description
Mixed hyperlipidaemia

2

Description of health condition studied
Diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Triglyceride
Timepoint
Before and 3 month after intervention
Method of measurement
paraclinical

2

Description
Cholesterol
Timepoint
Before and 3 month after intervention
Method of measurement
paraclinical

Secondary outcomes

1

Description
Liver aminotransferas(AST & ALT)
Timepoint
Before and 3 month after intervention
Method of measurement
Paraclinical

Intervention groups

1

Description
1oo or 200 mg Fenofibrate Tablet for 3 month
Category
Treatment - Drugs

2

Description
450 or 900 mg Gemfibrozil Tablet for 3 month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Dr .Mitra Niafar
Street address
Imam Reza hospital
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy of Tabriz University of Medical Sciences
Full name of responsible person

Dr Seid Kazem Shakori

Street address

Golgasht Street ,Tabriz University of Medical Sciences ,central building II,third floor

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research deputy of Tabriz University of Medical Sciences

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mitra Niafar

Position

Associate profeesor- endocrinologist

Other areas of specialty/work

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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