

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Compare the effects of pioglitazone with fenofibrate in treatment of patients with NAFLD

Protocol summary

Summary

This study aimed to investigate the Compare the effects of fenofibrate with pioglitazone treatment of patients with NAFLD, as a clinical trial study. And 90 patients with proven NAFLD by ultrasonography and ALT more than 1.5 to 5 times the normal, BMI between 25 to 29.9 with the written consent referred to the gastroenterology clinic in Vali Asr hospital or private offices to be studied. And weight, blood pressure, BMI, liver function tests, blood glucose, and lipid profiles are analyzed. Both groups will be referred to a dietitian. Then randomly divided into three groups (30 people). The control group will have a daily exercise for at least 30 minutes. The intervention group A will receive fenofibrate capsule 200 mg once daily after a meal and the intervention group B receive pioglitazone tablet 30 mg once daily after a meal . After 12 weeks of starting treatment the above cases, re-evaluated by same person in the same laboratory unit. Information collected will be evaluated and compared. And fenofibrate with pioglitazone impact in the treatment of NAFLD and reducing liver enzymes checked. In this study, reducing the amount of ALT as the primary outcome and improvement of fatty liver was considered as a secondary outcome.

General information

Acronym

Compare the effects of pioglitazone with fenofibrate in treatment of patients with NAFLD

IRCT registration information

IRCT registration number: **IRCT2015120819554N10**
Registration date: **2016-07-12, 1395/04/22**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-12, 1395/04/22

Registrant information

Name

Maryam Jameshorani

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

dr.shirinjameshorani@zumc.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Zanjan University Of Medical Sciences

Expected recruitment start date

2016-07-20, 1395/04/30

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effects of pioglitazone with fenofibrate in treatment of patients with NAFLD

Public title

Compare the effects of pioglitazone with fenofibrate in treatment of patients with NAFLD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with NAFLD on

ultrasonography; ALT more than 1.5 to 5 times the normal range; BMI between 25 to 29.9 Exclusion criteria: Alcoholic hepatitis; systemic or metabolic or inflammatory disease such as diabetes; viral hepatitis; autoimmune hepatitis; secondary fatty liver disease such as drug induced fatty liver disease

Age

From **30 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Zanjan University of Medical Sciences

Street address

Medical School, Zanjan University of Medical Sciences, Karmandan street, Zanjan

City

zanjan

Postal code

4514938471

Approval date

2014-05-04, 1393/02/14

Ethics committee reference number

zums.rec.1393.133

Health conditions studied

1

Description of health condition studied

Nonalcoholic steatohepatitis

ICD-10 code

K75.8

ICD-10 code description

Other specified inflammatory liver diseases, Nonalcoholic

steatohepatitis [NASH]

Primary outcomes

1

Description

ALT

Timepoint

once at the beginning and the second time after twelve weeks

Method of measurement

ELIZA

2

Description

FBS

Timepoint

once at the beginning and the second time after twelve weeks

Method of measurement

ELIZA

3

Description

lipid profile

Timepoint

once at the beginning and the second time after twelve weeks

Method of measurement

ELIZA

Secondary outcomes

1

Description

Improve fatty liver

Timepoint

once at the beginning and the second time after twelve weeks

Method of measurement

Specific liver enzyme tests

Intervention groups

1

Description

Tab pioglitazone 30 mg once a day

Category

Treatment - Drugs

2

Description

Tab fenofibrat 200 mg once aday

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr.maryam jameshorani

Street address

Valiasr Hospital Valiasr sq Zanjan

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Zanjan University Of Medical Sciences

Full name of responsible person

Dr. Maryam Jameshorani

Street address

Zanjan,Azadi Square, Zanjan University Of Medical Sciences.

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Zanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research, Zanjan 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

Zanjan,University Of Medical Sciences

Full name of responsible person

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Position

Internist

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