Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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
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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
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 begining and the second time after twelve weeks

Method of measurement
ELIZA

2

Description
FBS

Timepoint
once at the begining and the second time after twelve weeks

Method of measurement
ELIZA

3

Description
lipid profile

Timepoint
once at the begining and the second time after twelve weeks

Method of measurement
ELIZA

Secondary outcomes

1

Description
Improve fatty liver

Timepoint
once at the begining 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
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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.
City
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
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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