Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the therapeutic effects of pioglitazone and metformin in non-alcoholic fatty liver disease

Protocol summary

Study aim
Comparison of the therapeutic effect of pioglitazone and metformin in patients with NAFLD based on laboratory findings and liver imaging

Design
One-blind clinical trial with two intervention groups including patients with non-alcoholic fatty liver over 18 years of age who are randomly divided into two groups of 55 based on a random number table.

Settings and conduct
This study is a one-sided blind trial in which patients with alcoholic fatty liver referred to gastrointestinal clinics affiliated to Oroumia University of Medical Sciences in Oroumia, West Azerbaijan Province will be studied from November 2021 to March 2022 which include inclusion criteria. . In this study, patients are divided into two groups completely randomly using a table of random numbers with a simple random method. A total of 110 patients will be randomly divided into two intervention groups of 55 (the first group receiving metformin 500 mg twice daily and the second group receiving pioglitazone 30 mg daily) will be included in the study.

Participants/Inclusion and exclusion criteria
Patients with NAFLD over 18 years of age who have not exclusion criteria (alcohol consumption, chronic and acute viral hepatitis and autoimmunity, type 1 diabetes, cholestatic diseases including cholecystitis, pregnancy and lactation, history of pioglitazone use, metformin NSAIDs, Fibrates and Statins, Kidney Disease, Thyroid Disease, Types of Malignancies, Severe Infectious Diseases, Cardiovascular Disease and Immune Deficiency, History of Corticosteroids and Steroid Compounds in the Last Three Months Do not have strenuous exercise or drug intolerance)

Intervention groups
The first group received metformin 500 mg twice daily and the second group received pioglitazone 30 mg daily.

Main outcome variables
Fasting blood sugar, level of liver enzymes, lipid profile, hepatic ultrasound findings

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211014052767N1**
Registration date: **2021-11-09, 1400/08/18**
Registration timing: **prospective**

Last update: **2021-11-09, 1400/08/18**
Update count: **0**

Registration date
2021-11-09, 1400/08/18

Registrant information

Name
Siavash vakili

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 87 3623 6558

Email address
siavash.v75@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-18, 1400/08/27

Expected recruitment end date
2022-03-18, 1400/12/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the therapeutic effects of pioglitazone and metformin in non-alcoholic fatty liver disease

Public title
Therapy of non alcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Grade 2 and 3 non-alcoholic fatty liver disease based on the latest ultrasound findings

Exclusion criteria:
History of long term alcohol consumption History chronic and acute viral and autoimmune hepatitis, type 1 diabetes, cholestatic diseases including cholecystitis, kidney, thyroid disease, various malignancies, severe infectious diseases, cardiovascular disease and immune deficiency History of pioglitazone, metformin, NSAIDs, fibrates, statins and warfarin Pregnancy and lactation History of corticosteroids and steroid compounds in the last three months Controlled diet or strenuous exercise

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Using a simple random number table, patients will be divided into two intervention groups (the first group receiving metformin 500 mg twice daily and the second group receiving pioglitazone 30 mg daily).

Blinding (investigator's opinion)
Single blinded

Blinding description
After obtaining informed consent, patients will be randomly divided into two study groups, where each group will receive their intervention drug indefinitely from the researcher, and during the study, patients will not know the type of drug they received.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Oroumia University of Medical Sciences

Street address
Oroumia University of Medical Sciences headquarter , Resalat ave. , Emergency alley

City
Oroumia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2021-10-01, 1400/07/09

Ethics committee reference number
IR.UMSU.REC.1400.250

Health conditions studied

1

Description of health condition studied
Non alcoholic fatty liver disease

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Liver sonographic findings

Timepoint
At the beginning of the study and 3 months after the start of the drug intervention

Method of measurement
Based on the classification of fatty liver

2

Description
Liver enzymes

Timepoint
At the beginning of the study and 3 months after the start of the drug intervention

Method of measurement
Laboratory data

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: will recieve Tab. Metformin 500 mg twice daily (BID) oral for 3 months (Raha pharmaceutical Co.)
Category
Treatment - Drugs

2

Description
Intervention group 2: will recieve Tab. Pioglitazone 30 mg daily oral for 3 months (Hakim Pharmaceutical Co.)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Siavash Vakili
Street address
Ershad street, Oroumia
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5714783734
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+98 44 3223 4897
Email
imamhospital@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj mohebbi
Street address
Research and Technology Deputy Building , Oroumia University of Medical Sciences headquarters, Emergency alley , Resalat Blvd , Oroumia
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5714783734
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+98 44 3193 7224
Email
research@umsu.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Siavash Vakili
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Demographic information data and the main outcomes of the study will be shareable after identifying individuals.

When the data will become available and for how long
Access period begins 6 months after publication of study results

To whom data/document is available
The data will be available to researchers in research centers

Under which criteria data/document could be used
Performing any analysis on the data that can be published is unrestricted for the applicants

From where data/document is obtainable
Siavash Vakili, Siavash.v75@gmail.com

What processes are involved for a request to access data/document
The applicant can request access to the data via email to the respondent. The data will be provided to the applicant within 3 months after checking the conditions

Comments