

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of the therapeutic effect of pioglitazone and metformin on ultrasound scoring and liver enzymes in patients with non alcoholic fatty liver disease

Protocol summary

Study aim

A comparison of the effect of pioglitazone and VitE 800, metformin and Vit E800 on liver enzymes in two groups of interventions; The effect of concomitant administration of pioglitazone and VitE 800, metformin and Vit E800 on liver ultrasonography in two groups of interventions

Design

Clinical trial of random intervention

Settings and conduct

Patients with fatty liver disease who referred to Vali Asr Hospital

Participants/Inclusion and exclusion criteria

Patients aged 18-65 years old; patients who have been diagnosed with non-alcoholic fatty liver on the basis of ultrasound evidence and tests.

Intervention groups

The first group received pioglitazone mg 30 and VitE 800, and the second group received metformin 1 gr and vitamin E 800 for 6 months.

Main outcome variables

Enzyme Level AST; enzyme Level ALT; Disease grade by ultrasound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023083N2**

Registration date: **2019-09-23, 1398/07/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-23, 1398/07/01**

Update count: **0**

Registration date

2019-09-23, 1398/07/01

Registrant information

Name

Haleh Rezaee

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 2250

Email address

rezaeeha@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-18, 1398/02/28

Expected recruitment end date

2019-10-20, 1398/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of pioglitazone and metformin on ultrasound scoring and liver enzymes in patients with non alcoholic fatty liver disease

Public title

Effect of metformin and pioglitazon in treatment of fatty liver

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18_65 years old Patients based on ultrasound

evidence and testing of non-alcoholic fatty liver

Exclusion criteria:

People under the age of 18 Pregnant and lactating women People with kidney failure 30> GFR People with heart failure HF Class 3 and 4 People with liver cirrhosis

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization tool: such as random number table, sealed envelope, statistical software ..

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

No.27, Niaaran ave., Abiari blvd., El Goli

City

Tabriz

Province

East Azarbaijan

Postal code

5168659895

Approval date

2019-05-18, 1398/02/28

Ethics committee reference number

IR.TBZMED.REC.1398.226

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

Serum Spartate Aminotransferase Level

Timepoint

On arrival and after intervention

Method of measurement

Laboratory methods with Kits

2

Description

Grade sonography

Timepoint

On arrival and after intervention

Method of measurement

Ultrasound machine

3

Description

Serum levels of alanine amino transferase

Timepoint

On arrival and after intervention

Method of measurement

Laboratory methods with Kits

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the first group received pioglitazone 30 mg for 6 months

Category

Treatment - Drugs

2

Description

Intervention group: second group received metformin 1 gr and VitE 800 for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Vali Asr Hospital

Full name of responsible person

Manochehr Khoshbaten

Street address

No. 27, Irrigation Flake, Villasher, Tabriz

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shahrzadshayan@yahoo.com

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Haleh Rezaee

Position

Academic member, Assistant Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Web page address<http://www.tbzmed.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Web page address<http://www.tbzmed.ac.ir/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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 scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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داروسازی بالینی PhD
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available