Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Comparison of the theraputic effect of pioglitazone and metformin on ultrasound scoring and liver enzymez in potients 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 theraputic effect of pioglitazone and metformin on ultrasound scoring and liver enzymez in potients 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
City
Tabriz
Province
East Azarbaijan
Postal code
1376656763
Phone
+98 41 3383 0243
Email
shahrzadshayan@yaho.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Haleh Rezaee
Street address
Faculty of Pharmacy, First floor, Department of Clinical Pharmacy, University Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
51664-14766
Phone
+98 41 3337 2250
Fax
Email
rezaeeha@tbzmed.ac.ir
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 general inquiries

Contact
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
Street address
Faculty of Pharmacy, First floor, Department of Clinical Pharmacy, University Street, Tabriz
City
Tabriz
Province
Azarbayjan Shargi
Postal code
51664-14766
Phone
+98 41 3337 2250
Fax
Email
rezaeeha@tbzmed.ac.ir
Web page address
http://www.tbzmed.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Haleh Rezaee
Position
PhD of Clinical Pharmacy
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, First floor, Department of Clinical Pharmacy, University Street,Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
51664-14766
Phone
+98 41 3337 2250
Email
Rezaeeha@tbzmed.ac.ir
Web page address
http://www.tbzmed.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Haleh Rezaee

Position

PhD داروسازی بالینی

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, First floor, Department of Clinical Pharmacy, University Street,Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3337 2250

Email

Rezaeeha@tbzmed.ac.ir

Web page address

http://www.tbzmed.ac.ir/

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