

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the therapeutic effect of metformin and L-carnitine on ultrasound scoring and liver enzymes in patients with non-alcoholic fatty liver

Protocol summary

Study aim

A comparison of the effect of L-carnitine and VitE800, metformin and vit / E800 on liver enzymes in two groups of intervention/The effect of concomitant administration of L-carnitine and VitE 800, metformin and vit / E800 on liver ultrasonography in two groups of intervention

Design

Clinical trial of random intervention

Settings and conduct

Patients with fatty liver and referred to Vali Asr Hospital

Participants/Inclusion and exclusion criteria

Patients aged 18-65 years 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 VitE800, and the second group received metformin 1 and vitamin E 800 for 6 months.

Main outcome variables

Enzyme Level AST Enzyme Level ALT Grade ultrasound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023083N3**

Registration date: **2019-12-29, 1398/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-29, 1398/10/08**

Update count: **0**

Registration date

2019-12-29, 1398/10/08

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

2019-08-20, 1398/05/29

Expected recruitment end date

2020-02-18, 1398/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of metformin and L-carnitine on ultrasound scoring and liver enzymes in patients with non-alcoholic fatty liver

Public title

Effect of metformin and L-carnitine 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 was done using Randomized Block -size 4 method.

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

IR.TBZMED.REC.1398.544

Street address

No.20, baharan ave, vilashahr blvd, El golu

City

Tabriz

Province

East Azarbaijan

Postal code

5168755888

Approval date

2019-08-19, 1398/05/28

Ethics committee reference number

IR.TBZMED.REC.1398.544

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

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:The first group received L-carnitine 1 g and VitE800 for 6 months

Category

Treatment - Drugs

2

Description

Intervention group :the second group received metformin 1g and Vit E 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

aflaknema, Villasher hospital

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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, 6th floor, Department of Clinical Pharmacy, University Street, Tabriz

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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

PHD of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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