Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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)

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+98 41 3337 2250

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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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5168755888

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+98 41 3382 6340

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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
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Faculty of Pharmacy, 6th floor, Department of Clinical Pharmacy, University Street, Tabriz
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rezaeeha@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
PHD of Clinical Pharmacy
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Medical Pharmacy
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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