

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5168755888

##### Phone

+98 41 3382 6340

##### Email

ali.hossainzadeh2016@gmail.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, 6th 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

**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

**Street address**

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

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**Web page address**<http://www.tbzmed.ac.ir>**Person responsible for updating data****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