

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

comparison the therapeutic effect of pioglitazone and carnitine to pioglitazone and vitamin E in patients with non alcoholic fatty liver disease

Protocol summary

Study aim

Determination of the efficacy of pioglitazone and carnitine in comparison with pioglitazone and vitamin, in ultrasound and liver enzymes in patients with non-alcoholic fatty liver disease (NAFLD)

Design

In this randomized single-blind study patients with the EXCEL program will be randomly divided into 2 groups of receiving Pioglitazone and carnitine and receiving Pioglitazone and vitamin E. The sample size will be selected by the G-power software to a number of 40 people per group and 80 people in total. And these people will be selected as random from the list of patients.

Settings and conduct

This study will be performed on patients of Tabriz Valiasr hospital with non-alcoholic fatty liver.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with non alcoholic fatty liver disease (ruled out all other known causes). Exclusion criteria: Patients with liver diseases such as viral hepatitis, Autoimmune hepatitis, Wilson, Hemochromatosis, Cirrhosis of the liver and PBC and PSC, alcohol consumption, kidney failure, severe systemic disease and known malignancy, pregnant and lactating women and patients with type 1 diabetes.

Intervention groups

Intervention group: Pioglitazone (30 mg daily) and Carnitine (1000 mg daily) Control group: Pioglitazone (30mg daily) and Vitamin E (800mg daily)

Main outcome variables

Ultrasound grade; AST serum level; ALT serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190701044062N8**

Registration date: **2021-09-26, 1400/07/04**

Registration timing: **retrospective**

Last update: **2021-09-26, 1400/07/04**

Update count: **0**

Registration date

2021-09-26, 1400/07/04

Registrant information

Name

manouchehr khoshbaten

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 3010

Email address

mkhoshbaten@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison the therapeutic effect of pioglitazone and carnitine to pioglitazone and vitamin E in patients with

non alcoholic fatty liver disease

Public title

comparison the therapeutic effect of pioglitazone and carnitine to pioglitazone and vitamin E in patients with non alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with non alcoholic fatty liver disease

Exclusion criteria:

Patients with liver disease such as viral hepatitis, autoimmune hepatitis, Wilson, hemochromatosis, liver cirrhosis, and PBC and PSC Patients who drink alcohol Patients with renal Failure (Creatinine > 1.5 mg/dl) Patients with known severe systemic disease and malignancy. Pregnancy or breastfeeding Patients with type 1 diabetes

Age

From **17 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using GraphPad software. So that the random sequence for the two groups will be determined by a person who has no role in other parts of the research using this software. Patients will then be assigned to each of the groups of pioglitazone and carnitine or pioglitazone and vitamin E depending on the clinic visit. Our colleague will place the group plan in a sealed envelope and present it to the patient to take to the researcher proving the drugs and receive the drug group. The sequence will remain with the researcher until the end of the study. The output of the software is A and B and people will be randomly assigned to each of groups A and B. The labels of groups A and B will be affixed to the intervention packages or placebo by a person who has no role in other parts of the research, and at the end of the study, after statistical analysis, the content of groups A and B will be determined.

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5165663755

Approval date

2019-10-01, 1398/07/09

Ethics committee reference number

IR.TBZMED.REC.1398.663

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

Liver enzymes levels

Timepoint

At baseline, 3 and 6 months after the intervention

Method of measurement

Laboratory methods

2

Description

Ultrasound grade

Timepoint

At baseline and 6 months after intervention

Method of measurement

Perform liver ultrasound

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group: pioglitazone 30mg daily and carnitine 1000mg daily for 6 months

Category

Treatment - Drugs

2

Description

Control group: pioglitazone 30mg daily and vitamin E 800mg daily for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Manouchehr Khoshbaten

Street address

Aflaknoma Squ, Niayesh Blvd

City

Tabriz

Province

East Azarbaijan

Postal code

5166618564

Phone

+98 41 3327 3000

Fax

+98 41 3332 8833

Email

tvaliasrhospital@gmail.com

Web page address

<http://tabrizhospital.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ata Mahmoodpour

Street address

Golgasht Ave, Imam Reza Hospital Clinic, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5154751637

Phone

+98 41 3337 2084

Email

a.mahmoodpour@gmail.com

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

Manouchehr Khoshbaten

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterologist and Hepatologist

Street address

Golgasht Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5166618564

Phone

+98 41 3336 0840

Email

mkhoshbaten@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Manouchehr Khoshbaten

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterologist and Hepatologist

Street address

Golgasht Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5166618564

Phone

0984133360840

Email

mkhoshbaten@yahoo.com

East Azarbaijan

Postal code

5166648564

Phone

+98 41 3336 0840

Email

mkhoshbaten@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Manouchehr Khoshbaten

Position

Professor

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Subspecialist

Other areas of specialty/work

Gastroenterologist and Hepatologist

Street address

Golgasht Ave

City

Tabriz

Province**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available