Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

comparison the teraputic effect of pioglitazone and carnitine to metformin and carnitine in patients with non alcoholic fatty liver disease

Protocol summary

Study aim
Determination of the efficacy of carnitine and pioglitazone in comparison with carnitine and metformin, in ultrasound and liver enzymes in patients with non-alcoholic fatty liver disease

Design
Patients will be randomly divided into two groups using carnitine and pioglitazone and carnitine and metformin recipients using the Excel program. Sample size using G-power software and considering 90% power and 95% confidence level and probable 30% loss and using ALT results in the study of hong et al, In 2014, at least 30 individuals in each group and 60 persons in total were calculated and in this study 40 persons per group and 80 persons in total were selected.

Settings and conduct
This study performed in patients with non-alcoholic fatty liver who were randomly assigned to the intervention (carnitine and pioglitazone) and control groups (carnitine and metformin) in a 1: 1 ratio with the help of Excel. Patients admitted to the liver fatty clinic who have evidence of liver fever on ultrasound will be included or excluded from the study through inclusion and exclusion criteria and with informed consent.

Participants/Inclusion and exclusion criteria
Paitents with NAFLD who have been ruled out all known causes of fatty liver disease including alcohol, medications, viral hepatitis, autoimmune hepatitis and metabolic causes such as Wilson and hemochromatosis and etc. Patients with liver disease such as viral hepatitis, autoimmune hepatitis, Wilson, hemochromatosis, liver cirrhosis, and PBC and PSC,Patients who drink alcohol.Patients with Creatinine > 1.5 mg/dl, Patients with known severe systemic disease and malignancy.Pregnancy or breastfeeding. type 1 diabetes

Intervention groups
Intervention group: carnitine (1000 mg daily) and pioglitazone (30mg daily) Control group: carnitine (1000 mg daily) and metformin (500 mg daily)

Main outcome variables
Ultrasound grade; AST serum level; ALT serum level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190701044062N3**
Registration date: **2020-09-16, 1399/06/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-16, 1399/06/26**
Update count: **0**

Registration date
2020-09-16, 1399/06/26

Registrant information

Name
manouchehr khoshbaten

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 1334 3010

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-22, 1398/07/30

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison the teraputic effect of pioglitazone and carnitine to metformin and carnitine in patients with non alcoholic fatty liver disease

Public title

comparison the teraputic effect of pioglitazone and carnitine to metformin and carnitine in patients with non alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

17-50 years old Paitents with non alcoholic fatty liver disease who have been ruled out all known causes of fatty liver disease including alcohol, medications, viral hepatitis, autoimmune hepatitis and metabolic causes such as Wilson and hemochromatosis and etc.

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

Given the fact that the sample size is the same in both groups, we use the Excel software to randomise. Patients will be randomly divided into two groups of carnitine and pioglitazone and carnitine and metformin.

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

Central Office of Tabriz University of Medical Sciences Tabriz -Golghast St.- Azadi St.

City

tabriz

Province

East Azarbaijan

Postal code

5165663755

Approval date

2019-06-11, 1398/03/21

Ethics committee reference number

IR.TBZMED.REC.1398.270

Health conditions studied

1

Description of health condition studied

non alcoholic fatty liver disease (NAFLD)

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Liver enzymes levels before and after carnitine and pioglitazone administration

Timepoint

At baseline and 3 months later and 6 months after the intervention

Method of measurement

Laboratory methods

2

Description

Ultrasound grade determination before and after carnitine and pioglitazone

Timepoint

At baseline and 6 months after intervention

Method of measurement

Perform liver ultrasound

3

Description

Liver enzymes levels before and after carnitine and metformin

Timepoint

At baseline and 3 months later and 6 months after the intervention

Method of measurement

laboratory methods

4

Description

Ultrasound grade determination before and after carnitine and metformin

Timepoint

At baseline and 6 months after intervention

Method of measurement

Perform liver ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For this group of patients, 1000 mg of carnitine and 30 mg of pioglitazone will be prescribed daily for 6 months. Drugs, especially carnitine, are available at different times at different brands due to the embargo conditions. No specific brand is used and only generic drugs are used. We do not have special equipment. Carnitine with 2 tablets of 500 mg in the morning and evening and pioglitazone with a dose of 30 mg tablets daily is given at noon. Patients are followed every three months and the side effects and intolerance of the drug are checked and in the absence of problems and in case of correct and complete use of the prescribed drug, the second 3-month period is prescribed.

Category

Treatment - Drugs

2

Description

Intervention group: For this group of patients, 1000 mg of carnitine and 500 mg of metformin will be prescribed daily for 6 months. Drugs, especially carnitine, are available at different times at different brands due to the embargo conditions. No specific brand is used and only generic drugs are used. We do not have special equipment. Carnitine with 2 tablets of 500 mg in the morning and evening and metformin with a dose of 500 mg tablets daily is given at noon. Patients are followed every three months and the side effects and intolerance of the drug are checked and in the absence of problems and in case of correct and complete use of the prescribed drug, the second 3-month period is prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Manouchehr Khoshbaten

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tvaliasrhospital@gmail.com

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http://tabrizhospital.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ata Mahmodpour

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Golgasht Ave, imam reza hospital clinic

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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

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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