Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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)
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+98 41 1334 3010
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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
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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
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http://tabrizhospital.ir

Sponsors / Funding sources

1

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Full name of responsible person
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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
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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