Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Study of the efficacy of coadministration of Pioglitazone and Vitamin E compared to coadministration Metformin and Ursodeoxycholic acid (UDCA) on ultrasound scoring and liver enzymes in patients with non-alcoholic fatty liver

Protocol summary

Study aim
The effect of concomitant administration of Pioglitazone and Vitamin E in comparison with the simultaneous administration of Metformin and Ursodeoxycholic acid in improving patients with non-alcoholic fatty liver

Design
Block randomized, Clinical trial, phase 3

Settings and conduct
This study will be conducted on patients with non-alcoholic fatty liver who are referred to the Center for Applied Scientific Research. A group of patients will receive Pioglitazone 15 mg plus Vitamin E 800 IU and another Metformin plus UDCA for 6 months on an daily basis. At the start of the study, 3 months after and at the end of the study blood samples will be taken from all subjects to measure the level of liver enzymes. Also at this intervals, patients will be screened by ultrasound for fatty liver gradients. Measuring the level of liver enzymes in the Danesh lab and performing ultrasound in the Tabesh imaging center.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 18-65 years; patients who have been diagnosed with non-alcohol fatty liver based on ultrasound and tests; People with diabetes controlled (HbA1C below 8%) Exclusion criteria: People with heart failure (HF) classes 3 and 4; People with renal insufficiency (GFR <30); People with bladder cancer; patients with osteoporosis; pregnant and lactating women

Intervention groups
Intervention group 1: Pioglitazone plus vitamin E
Intervention group 2: Metformin plus Ursodeoxycholic acid

Main outcome variables
Liver Enzymes (AST; ALT) Ultrasound grade

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180404039187N1**
Registration date: **2018-11-22, 1397/09/01**
Registration timing: **prospective**

Last update: **2018-11-22, 1397/09/01**
Update count: **0**

Registration date
2018-11-22, 1397/09/01

Registrant information

Name
Elnaz Shaseb

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-21, 1397/09/30

Expected recruitment end date
2019-02-20, 1397/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Study of the efficacy of coadministration of Pioglitazone and Vitamin E compared to coadministration Metformin and Ursodeoxycholic acid (UDCA) on ultrasound scoring and liver enzymes in patients with non-alcoholic fatty liver

Public title
"Evaluation of the effect of Pioglitazone and Vitamin E in Fatty Liver", "The effect of Metformin and UDCA on Fatty Liver"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18-65 years Patients who have been diagnosed with non-alcoholic fatty liver based on ultrasound evidence and tests People with controlled diabetes (HbA1C below 8%)

Exclusion criteria:
People with heart failure (HF) Classes 3 and 4 People with kidney failure (GFR <30) People with liver cirrhosis People with bladder cancer People with Osteoporosis Pregnant and lactating women alcohol consumption People who also use other vitamins containing vitamin E at the same time People receiving warfarin

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **158**

Randomization (investigator's opinion)
Randomized

Randomization description
Random method and description of each method: simple randomization, block Arrange the accident stages: 1) Determine the volume of each block (Foursquare blocks) 2) Prepare block lists and assign numbers to them AABB(1) ABAB(2) ABBA(3) BBAA(4) BABA(5) BAAB(6) 3) Selection of random numbers between 1 and 6 4) Identification of the Treatment Assignment For example: AABB(1)_BBAA(4)_ABAB(2)_BABA(5)

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
Research & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golghast St, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2018-08-27, 1397/06/05

Ethics committee reference number
IR.TBZMED.REC.1397.445

Health conditions studied

1

Description of health condition studied
Fatty liver

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Grade ultrasound

Timepoint
At the beginning of the study, 3 months and 6 months later

Method of measurement
Sonography

2

Description
Liver Enzymes(AST , ALT)

Timepoint
At the beginning of the study, 3 months and 6 months later

Method of measurement
Blood test

Secondary outcomes

1

Description

Lipid profile

Timepoint

At the beginning of the study, 3 and 6 months later

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group 1: Individuals receiving Pioglitazone plus Vitamin E: People in this group will receive Pioglitazone 15 mg and Vitamin E 800 mg (400 mg twice daily, Zahravi factory) on a daily basis for 6 months, as well as all patients at the time of arrival, Three months later, at the end of the study (6 months later), blood samples were taken to determine the level of liver enzymes and ultrasound to determine the grade of fatty liver. Measuring the level of liver enzymes in the "Danesh" lab and doing ultrasound at the "Tabesh" imaging center

Category

Treatment - Drugs

2

Description

Intervention group 2: Individuals receiving Metformin plus Ursodeoxycholic acid: People in this group will receive Metformin at a dose of 500 mg daily and Ursodeoxy cholic acid at a dose of 300 mg (three times a day, making a So.se Italian factury) on a daily basis for 6 months, as well as all patients at the time of arrival, Three months later, at the end of the study (6 months later), blood samples were taken to determine the level of liver enzymes and ultrasound to determine the grade of fatty liver. Measuring the level of liver enzymes in the "Danesh" lab and doing ultrasound at the "Tabesh" imaging center

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Teaching Hospital of Tabriz

Full name of responsible person

Manuchehr khoshbaten MD

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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

30

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 Elnaz Shaseb

Position

Member of the faculty of clinical pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Position
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Other areas of specialty/work
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Medical doctor

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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