

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Aug 2026

Comparison of the therapeutic effect of empagliflozin with pioglitazone and vitamin E on non-alcoholic fatty liver in patients with type 2 diabetes

Protocol summary

Study aim

Comparison of the effect of empagliflozin with pioglitazone and vitamin E on liver enzymes and grades of fatty liver in type 2 diabetic patients with nonalcoholic fatty liver

Design

This is a randomized study with parallel groups on 66 patients to control diabetic patients with fatty liver with empagliflozin or pioglitazone and vitamin E. The subjects are randomly assigned to 1: 1 ratios in the intervention or control groups.

Settings and conduct

This study performed in patients with non-alcoholic fatty liver and diabetic who were assigned to the intervention and control groups. Patients who have evidence of fatty liver on ultrasound will be included or excluded to the study through inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Patients with non-alcoholic fatty liver disease (NAFLD) are referred to the Valiasr Hospitals in Tabriz. Inclusion criteria included: patients 18 - 75 years, BMI <45 kg / m², a known case of type 2 diabetes used by metformin, a known case of fatty liver, HbA1c are between 6-8%. Exclusion criteria also included History of hypoglycemia liver disease Other than non-alcoholic fatty liver Previous use of thiazolidinedione treatment, immunomodulatory, antiobesity, anti-NASH glucagon-like peptide 1 agonists, sodium-glucose cotransporter 2 inhibitors, or vitamin E, amiodarone, tamoxifen, methotrexate In the last six months, severe heart, lung and kidney disease, Contraindications to the use of empagliflozin, Uncontrolled type 2 diabetes, Changes in diet and activity during the study.

Intervention groups

Intervention group will receive daily empagliflozin 10mg and metformin for 12 weeks, and the other group will receive daily pioglitazone 30 mg and vitamin E and metformin daily for 12 weeks.

Main outcome variables

Levels of AST, ALT and grades of fatty liver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190701044062N4**

Registration date: **2021-01-19, 1399/10/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-19, 1399/10/30**

Update count: **0**

Registration date

2021-01-19, 1399/10/30

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

2020-11-23, 1399/09/03

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of empagliflozin with pioglitazone and vitamin E on non-alcoholic fatty liver in patients with type 2 diabetes

Public title

Comparison of the therapeutic effect of empagliflozin with pioglitazone and vitamin E on non-alcoholic fatty liver in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 75 years old BMI <45 kg/m² A known case of type 2 diabetes used by metformin A known case of non-alcoholic fatty liver HbA1c 6-8%

Exclusion criteria:

History of hypoglycemia liver disease Other than non-alcoholic fatty liver Previous use of thiazolidinedione treatment, immunomodulatory, antiobesity, anti-NASH glucagon-like peptide 1 agonists, sodium-glucose cotransporter 2 inhibitors, or vitamin E, amiodarone, tamoxifen, methotrexate In the last six months severe heart, lung and kidney disease Contraindications to the use of empagliflozin (drug allergy, recurrence of genital urinary tract infection, history of recent or previous gangrene) Uncontrolled type 2 diabetes Changes in diet and activity during the study

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into control and intervention groups (1: 1). Patients will be assigned to two groups using the randomized block method. Patients will be divided into two equal groups using a random number table. STATA software will be used to generate a random sequence.

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 Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165663755

Approval date

2020-11-22, 1399/09/02

Ethics committee reference number

IR.TBZMED.REC.1399.796

Health conditions studied

1

Description of health condition studied

Non

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 vitamin E and pioglitazone administration

Timepoint

At baseline and 3 months after the intervention

Method of measurement

Laboratory methods

2

Description

Ultrasound grade determination before and after vitamin E and pioglitazone administration

Timepoint

At baseline and 3 months after the intervention

Method of measurement

liver ultrasonography

3

Description

Liver enzymes levels before and after empagliflozin

Timepoint

At baseline and 3 months after the intervention

Method of measurement

Laboratory methods

4

Description

Ultrasound grade determination before and after empagliflozin administration

Timepoint

At baseline and 3 months after the intervention

Method of measurement

liver ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will receive daily empagliflozin 10 mg and metformin daily for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients will receive daily pioglitazone 30 mg, vit E and metformin for 12 weeks.

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ata Mahmoodpour

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a.mahmoodpour@gmail.com

Web page address

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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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
No - There is not 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