

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Aug 2026

Evaluation of the effect of empagliflozin in combination with pioglitazone on fatty liver disease in type 2 diabetic patients referred to Imam Reza hospital during December 2022 to December 2023.

Protocol summary

Study aim

Investigating the effect of empagliflozin in combination with pioglitazone on the course of fatty liver disease in type 2 diabetic patients

Design

This study includes two groups that are randomly divided into two groups after matching in terms of age and sex. Both groups will receive medication.

Settings and conduct

This study will be done in Imam Reza Hospital. Diabetic patients who refer to the endocrinology clinic of this hospital will be included in the study after obtaining consent. The first group received pioglitazone daily and the second group received pioglitazone plus empagliflozin, and then in terms of liver indices before and after the case study will be reviewed.

Participants/Inclusion and exclusion criteria

Inclusion criteria included T2DM and NAFLD based on fatty liver grade in liver ultrasound. Patients with grade 1 and above were included in the study. Exclusion criteria included type 1 diabetes, active or chronic hepatitis, cirrhosis and biliary disease, class III and IV heart failure, renal dysfunction, GFR<45, history of alcohol consumption (20 grams per day in women and 30 grams per day in men), consumption Non-steroidal anti-inflammatory drugs, use of supplements such as vitamin C, zinc, selenium or antioxidant agents, history of cardiovascular events in the last 3 months, pregnancy and breastfeeding, active cancer or history of cancer treatment in the last 2 years, untreated thyroid disorder or body mass index above 40 kg/m².

Intervention groups

Two groups of 42 and 43 people were included in the study. The first group will receive pioglitazone and the second group will receive daily pioglitazone plus empagliflozin.

Main outcome variables

Naflid fibrosis score%; APRI ratio %; FIB-4 index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240208060939N1**

Registration date: **2024-03-03, 1402/12/13**

Registration timing: **retrospective**

Last update: **2024-03-03, 1402/12/13**

Update count: **0**

Registration date

2024-03-03, 1402/12/13

Registrant information

Name

Afsaneh vosoghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4601 0322

Email address

afsaneh.vosoghi.1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of empagliflozin in combination with pioglitazone on fatty liver disease in type 2 diabetic patients referred to Imam Reza hospital during December 2022 to December 2023.

Public title

Evaluation of the effect of empagliflozin in combination with pioglitazone on fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having type 2 diabetes and fatty liver at the same time

Exclusion criteria:

Active or chronic hepatitis, cirrhosis and biliary disease

Class III and IV heart failure Renal dysfunction GFR<45

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were included in the study using available sampling method and after matching in terms of age and gender, they were divided into two groups, intervention and control.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of AJA University of Medical Sciences

Street address

Fatemi Street, Eetemad Zadeh street, Aja university of medical sciences

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2023-01-13, 1401/10/23

Ethics committee reference number

IR.AJAUMS.REC.1401.009

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**

AST,ALT

Timepoint

0, 24 Week after

Method of measurement

Laboratory

2**Description**

CAP score

Timepoint

0, 24 Week after

Method of measurement

Sonography/Fibro Scan

3**Description**

Nafld fibrosis score

Timepoint

0, 24 Week after

Method of measurement

D fibrosis score = $-1.675 + 0.037 \times \text{age}(\text{years}) + 0.094 \times \text{BMI}(\text{kg}/\text{m}^2) + 1.13 \times \text{IFG}/\text{diabetes}(\text{yes}=1, \text{no}=0) + 0.99 \times \text{AST}/\text{ALT ratio} - 0.013 \times \text{PLT} - 0.66 \times \text{albumin}$

4**Description**

APRI ratio

Timepoint

0, 24 Week after

Method of measurement

AST/PLT ratio

5

Description

FIB-4 index

Timepoint

0, 24 Week after

Method of measurement

Age (years)×AST (U/L)/[PLT(109/L)×ALT1/2 (U/L)]

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will receive 15 to 30 mg of pioglitazone daily for 24 weeks.

Category

Treatment - Drugs

2

Description

Control group: This group will receive 15 to 30 mg of pioglitazone plus 10 mg of empagliflozin daily for 24 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Afsaneh Vosoghi

Street address

Fatemi Street, Etemad zadeh street, AJA university of medical Sciences

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr Reza Mosaed

Street address

AJA University of Medical Sciences, Eetemad Zadeh Street, Fatemi Street

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afsaneh.vosoghi.1@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Afsaneh Vosoghi

Position

Internal Medicine Specialist

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Afsaneh Vosoghi

Position

Internal medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

afsaneh vosoghi

Position

Internal medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data will be made available in the form of articles

When the data will become available and for how long

Considering that the data will be available in the form of an article, there is no specific time frame for this.

To whom data/document is available

All the people who will have access to the article published in the journal.

Under which criteria data/document could be used

For the use of researchers

From where data/document is obtainable

The website of the journal in which the article was published

What processes are involved for a request to access data/document

So access to the journal site where the article is published and in accordance with the rules of the journal

Comments