

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Aug 2026

Comparison of high-dose and low-dose empagliflozin on fatty liver-related indices in patients with type 2 diabetes.

Protocol summary

Study aim

Evaluating the impact of high-dose empagliflozin on NAFLD indices in patients with T2DM to optimize clinical management, halt disease progression, and reduce complications and mortality associated with NAFLD.

Design

Randomized controlled trial with parallel groups on 56 patients, using alternating allocation in Excel for randomization.

Settings and conduct

Random assignment uses alternating allocation based on visit order, coordinated by the clinic secretary (uninvolved in analysis) at Chamran hospital, Tehran. Both tablet types are identical in size and shape, provided without extra info. Treatment lasts 24 weeks. Fatty liver is assessed via FIB-4, TyG, and FSI at start (for group equivalence) and end (for significant differences). Tests conducted in one lab. Blood pressure is taken seated, after 15 minutes rest, with an age- and arm-appropriate cuff.

Participants/Inclusion and exclusion criteria

Inclusion: Age 18-80. History of diabetes, defined as HbA1c > 6.4. Ultrasound indicating of NAFLD. Mental health and alertness. Glomerular filtration rate (GFR) above 60. Exclusion: SGLT2 inhibitor use in the past 3 months. Contraindication to SGLT2 inhibitors, including recurrent urinary infections and drug sensitivity. Secondary liver disease Cirrhosis. Use of corticosteroids, methotrexate, amiodarone, and other drugs that cause fatty liver. Alcohol addiction. Pregnancy. Failure to complete the follow-up period. Irregular use of empagliflozin.

Intervention groups

Patients with type 2 diabetes and NAFLD receiving empagliflozin 25 mg (high dose). Patients with type 2 diabetes and NAFLD receiving empagliflozin 10 mg (standard dose).

Main outcome variables

Framingham Steatosis Index (FSI): Assesses fatty liver

using age, BMI, diabetes and hypertension history, and TG, AST, ALT levels. FIB-4: Non-invasive index for liver fibrosis. TyG Index: Indicates insulin resistance, a marker for fatty liver.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250524065869N1**

Registration date: **2025-06-09, 1404/03/19**

Registration timing: **registered_while_recruiting**

Last update: **2025-06-09, 1404/03/19**

Update count: **0**

Registration date

2025-06-09, 1404/03/19

Registrant information

Name

Arian Shirani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8828 7600

Email address

shirani-a@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-09, 1404/03/19

Expected recruitment end date

2025-07-02, 1404/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of high-dose and low-dose empagliflozin on fatty liver-related indices in patients with type 2 diabetes.

Public title

Comparison of high-dose and low-dose empagliflozin on fatty liver-related indices in patients with type 2 diabetes.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age above 18 and below 80. History of diabetes, defined as HbA1c > 6.4. Ultrasound indicating of fatty liver. Mental health and alertness, with informed consent. Glomerular filtration rate (GFR) above 60.

Exclusion criteria:

History of SGLT2 inhibitor use in the past 3 months. Contraindication to SGLT2 inhibitors, including recurrent urinary-genital infections and drug sensitivity. Secondary liver disease; including viral hepatitis, autoimmune hepatitis, and cholestasis. Cirrhosis or advanced liver disease. Use of corticosteroids, methotrexate, amiodarone, and other drugs that cause fatty liver. Alcohol addiction. Pregnant women. Failure to complete the follow-up period. Irregular use of empagliflozin.

AgeFrom **18 years** old to **80 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **56****Randomization (investigator's opinion)**

Randomized

Randomization description

The randomization method will be alternate allocation; patients will be assigned to the first and second groups alternately based on the time of their first visit day (coordination of the sequence of patient entry will be handled by the clinic secretary, who has no role in the study analysis).

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**

Research Ethics Committees of AJA University of Medical Sciences

Street address

AJAUMS ,Etemadzadeh St., West Fatemi St.

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2025-05-06, 1404/02/16

Ethics committee reference number

IR.AJAUMS.REC.1404.009

Health conditions studied**1****Description of health condition studied**

Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

2**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**

Framingham Steatosis Index (FSI): If the calculated number is greater than zero, the likelihood of fatty liver increases; on the other hand, if the result is negative, it weighs against the presence of fatty liver.

Timepoint

At the initial visit and after 24 weeks from the start of treatment.

Method of measurement

History taking, Meter, Scale, Mercury blood pressure monitor and Standard laboratory.

2

Description

FIB-4: Non-invasive index for liver fibrosis.

Timepoint

At the initial visit and after 24 weeks from the start of treatment.

Method of measurement

Standard laboratory.

3

Description

Triglyceride-glucose (TyG) Index: Indicates insulin resistance, a marker for fatty liver.

Timepoint

At the initial visit and after 24 weeks from the start of treatment.

Method of measurement

Standard laboratory.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with type 2 diabetes and NAFLD receiving empagliflozin 25 mg (high dose). This tablet is prescribed daily for 24 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients with type 2 diabetes and NAFLD receiving empagliflozin 10 mg (standard dose). This tablet is prescribed daily for 24 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Hospital

Full name of responsible person

Farshid Mollaghasem Shemirani

Street address

Shahid Chamran Hospital, Fakhrazadeh St., Langari St., Nobonyad.

City

Tehran

Province

Tehran

Postal code

1693715814

Phone

+98 21 27956

Email

info@chamranhospital.ir

Web page address

https://www.chamranhospital.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Alireza Ranjbar Naeini

Street address

Artesh University of Medical Sciences, Etemadzadeh St., West Fatemi St

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8802 8350

Email

lab@ajaums.ac.ir

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

Farshid Mollaghasem Shemirani

Position

Deputy of Treatment

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

Street address

Shahid Chamran Hospital, Fakhrizadeh St., Langari St., Nobonyad

City

Tehran

Province

Tehran

Postal code

1693715814

Phone

+98 21 27956

Email

farshidshemirani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Farshid Mollaghasem Shemirani

Position

Deputy of Treatment

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

Street address

Shahid Chamran Hospital, Fakhrizadeh St., Langari St., Nobonyad

City

Tehran

Province

Tehran

Postal code

1693715814

Phone

+98 21 27956

Email

farshidshemirani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Farshid Mollaghasem Shemirani

Position

Deputy of Treatment

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

Street address

Shahid Chamran Hospital, Fakhrizadeh St., Langari St., Nobonyad

City

Tehran

Province

Tehran

Postal code

1693715814

Phone

+98 21 27956

Email

farshidshemirani@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Not applicable

Data Dictionary

No - There is not a plan to make this available