Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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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.
Age
From **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, Fakhrizadeh St., Langari St., Nobonyad.
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1693715814
Phone
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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
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1411718541
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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

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Person responsible for updating data

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Position
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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