Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Studying the effect of EMPAGLIFLOZIN on non-alcoholic fatty liver disease and liver fibrosis in type 2 diabetic patients

Protocol summary

Study aim
Studying the effect of EMPAGLIFLOZIN on non-alcoholic fatty liver disease and liver fibrosis in type 2 diabetic patients

Design
A phase 3 randomized, controlled clinical trial with parallel groups on 70 patients, and balanced block design was used for randomization.

Settings and conduct
This is an interventional study and clinical trial with a sample size of 70 people. Patients with type 2 diabetes, non-alcoholic fatty liver disease and liver fibrosis who refer to the Baghiye-Allah Clinic in Qom will be divided into two groups using a block randomization method after obtaining written consent: (Intervention group): Includes 35 patients who, in addition to standard treatment, receive empagliflozin at a dose of 10 mg once a day for 6 months. After administering the drug and after 6 months, tests and fibroscans will be repeated. The control group includes 35 patients who will receive standard treatment with placebo and after 6 months, tests and fibroscans will be repeated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with type 2 diabetes, Patients with grade 2 and 3 fatty liver regardless of fibrosis. Exclusion criteria:Patients with liver cirrhosis, Pregnancy and lactation, Renal failure

Intervention groups
Intervention group: After obtaining consent from eligible individuals through random sampling, in addition to standard treatment, they will undergo intervention with empagliflozin at a dose of 10 mg for 6 months. Control group: After obtaining consent from eligible individuals through random sampling, they will undergo standard diabetes treatment with placebo (that does not contain empagliflozin) for 6 months.

Main outcome variables
Degree of fatty liver by fibroscan before and 6 months after treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250316065096N1**
Registration date: **2025-05-10, 1404/02/20**
Registration timing: **prospective**

Last update: **2025-05-10, 1404/02/20**
Update count: **0**

Registration date
2025-05-10, 1404/02/20

Registrant information

Name
Mohamd Abedinifard

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 25 3336 8145

Email address
dr.abedinifard@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-22, 1404/03/01

Expected recruitment end date
2025-11-22, 1404/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Studying the effect of EMPAGLIFLOZIN on non-alcoholic fatty liver disease and liver fibrosis in type 2 diabetic patients

Public title
The effect of Empagliflozin on non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with type 2 diabetes Patients with grade 2 and 3 fatty liver regardless of fibrosis
Exclusion criteria:
Patients with liver cirrhosis Patients without fatty liver (hepatitis and drug side effects) Pregnancy and breastfeeding Kidney failure People who have received weight loss medications
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The allocation of individuals will be done using simple block randomization. The block size is considered to be 4. Therefore, we will have six blocks of four consisting of AABB, ABAB, BBAA, BABA, ABBA, BAAB. The selection of each block will also be random and will be done using a dice roll. For example, if the number 3 comes up in the dice roll, block BBAA is considered and therefore the first two patients will be assigned to treatment B and the next two patients to treatment A. The dice roll will continue until the allocation of patients to treatment groups is completed. Also, the allocation of treatment to groups A and B will also be done based on chance (random number table).
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee in research of Qom University of Medical Sciences
Street address
Ghadir Blvd
City
Qom
Province
Ghoum
Postal code
3736175513
Approval date
2025-01-22, 1403/11/03
Ethics committee reference number
IR.MUQ.REC.1403.225

Health conditions studied

1

Description of health condition studied
Nonalcoholic steatohepatitis (NASH)
ICD-10 code
K75.81
ICD-10 code description
Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description
Fatty liver grade on fibroscan
Timepoint
Before and 24 weeks after empagliflozin administration
Method of measurement
Fibroscan

Secondary outcomes

1

Description
Body Mass Index
Timepoint
Before and 24 weeks after empagliflozin administration
Method of measurement
Kg/m2

2

Description
Fasting blood sugar
Timepoint
Before and 24 weeks after empagliflozin administration
Method of measurement
Blood sampling

3

Description
HbA1C

Timepoint
Before and 24 weeks after empagliflozin administration
Method of measurement
Blood sampling

4

Description
level of liver transaminases
Timepoint
Before and 24 weeks after empagliflozin administration
Method of measurement
Blood sampling

Intervention groups

1

Description
Intervention group: , After obtaining consent, eligible individuals were randomly selected In addition to standard diabetes treatment, they receive the drug empagliflozin at a dose of 10 mg (Abidi Company) once a day for 6 months.
Category
Treatment - Drugs

2

Description
Control group: After obtaining consent, eligible individuals will be randomly assigned to receive a placebo drug without empagliflozin once daily for 6 months in addition to standard diabetes treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatullah Clinic, Qom
Full name of responsible person
Mohammad Abedini Fard
Street address
Alley No. 7 ,Shahid Fatemi Street
City
Qom
Province
Ghoum
Postal code
37719964797
Phone
+98 25 3774 1640
Email
Bmcqomclinic@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Mohammad Aghaali
Street address
No. 83, Shahid Lotfi Niaser Ave, Safashehr Blvd
City
Qom
Province
Ghoum
Postal code
3719964797
Phone
+98 912 751 5639
Email
aghaali2005@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Mohamd Abedinifard
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Beheshti Hospital, Beheshti Blvd, Qom, Iran
City
Qom
Province
Ghoum
Postal code
3719964797
Phone
+98 25 3336 8145
Fax
Email

dr.abedinifard@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Mohammad Bagherzadeh

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Endocrinology & Metabolism

Street address
Beheshti hospital; Shahid Beheshti Ave.

City
Qom

Province
Ghoum

Postal code
3719964797

Phone
+98 25 3612 2000

Email
m_bagherzadeh3@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Mohamd Abedinifard

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

Street address
Beheshti Hospital, Beheshti Blvd, Qom, Iran

City
Qom

Province
Ghoum

Postal code
3719964797

Phone
+98 25 3336 8145

Fax

Email
dr.abedinifard@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
Its release schedule is not yet known

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