Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of dapagliflozin effects on non-diabetic non-alcoholic fatty liver treatment

Protocol summary

Study aim
Investigating the effect of dapagliflozin on patients with non-alcoholic fatty liver disease

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 110 patients. For randomization, the table of random numbers was used using the website www.randomization.com.

Settings and conduct
This study is conducted on patients with non-alcoholic fatty liver disease who have referred to the liver clinic or endocrinology and metabolism outpatient clinic of Qaem Hospital located in Mashhad, Iran.For sampling, the envelope method is used:The envelopes will be prepared by a member of the research team and random numbers with the help of Randomaize.com and placed inside the envelope. The lid of the envelopes will be closed and its contents will not be visible from the outside. Then, first, the purpose of the study is explained to the person who meets the stated conditions, and if the person wishes, he signs the informed consent form and takes an envelope, then opens it, and based on the contents of the envelope, the person is entered into the intervention or control group.The analyst and the therapist do not know the type of treatment

Participants/Inclusion and exclusion criteria
Healthy subjects from general population aged between 20 and 65 years who have a controlled attenuation parameter (CAP) greater than or equal to 238dB/m on liver fiber scan will be included in the study.The exclusion criteria are hepatic and non-hepatic diseases, or the use of drugs that cause fatty liver, or treatment with other drugs that affect fatty liver.

Intervention groups
Patients in the intervention group will be given dapagliflozin 10 mg daily for three months

Main outcome variables
FBS, Chol, TG, LDL, HDL, AST, ALT performing fibroscan to determine the amount of liver fat in all patients at the beginning of the study and 3 months after the onset treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110727007134N2**
Registration date: **2025-01-25, 1403/11/06**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-25, 1403/11/06**
Update count: **0**

Registration date
2025-01-25, 1403/11/06

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
0511-6051105

Email address
mazoulomz881@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-20, 1403/11/01

Expected recruitment end date
2025-04-21, 1404/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of dapagliflozin effects on non-diabetic non-alcoholic fatty liver treatment

Public title
effects of Dapaglifozin on non-alcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Individuals from the general population aged between 20 and 65 years A controlled attenuation parameter (CAP) greater than or equal to 238dB/m in the liver fiber scan test

Exclusion criteria:
Known diseases including:Type 1 or 2 diabetes, acute or chronic liver disease, biliary tract disease, kidney or heart failure, active cancer or anticancer treatment within the past two years, untreated thyroid disease History of alcohol consumption drugs related to fatty liver such as continuous and daily use of non-steroidal anti-inflammatory drugs, amiodarone, tamoxifen, sodium valproate, methotrexate and corticosteroids, other drugs that affect fatty liver such as vitamin E and pioglitazone use of supplements such as vitamin C in the last month cardiovascular events in the last three months, pregnancy and breastfeeding, BMI greater than or equal to 40 kg/m2.

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
The random assignment of people to study groups while ensuring the equality of the sample size of the groups, the block method will be used as a reliable method of randomization that leads to the balanced allocation of people in treatment groups at the end of each block. For this purpose, we use the site: https://www.sealedenvelope.com/simple-randomiser/v1/lists. In this study, the size of the blocks is 6 and 8 and a total of 16 blocks consisting of 8 blocks of 6 and 8 blocks of 8 with different sequences are formed from both arms of the study at the output of the site.Next, each of the blocks is sealed in a non-transparent sealed envelope and all the blocks are randomly arranged. With the referral of each eligible patient, the first block is randomly selected and depending on the order of the sequence, the desired person is placed in one of the arms of the study.In the same way, after the completion of the first block, the second block is randomly selected and this continues until the last block and assigning the last person to the study arms. As a rule, by assigning the last sheet of the last block, the patients are grouped equally in the two arms of the study and the balance between the groups is established.

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the fact that the intervention and placebo drugs are prepared in similar packages in terms of appearance, size, and color, the patient will not be informed in which group he is placed. Also, the person evaluating the results will not be informed about the type of drug the patient is taking.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Faculty of Medicine, Mashhad University of Medical Sciences

Street address
Faculty of Medicine, Mashhad University Of Medical Sciences, Azadi Square, Mashhad, Khorasan Razavi Province, Iran

City
mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2024-05-28, 1403/03/08

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1403.108

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
Measurement of liver fat using controlled attenuation parameter
Timepoint
At the beginning of the study and after 3 months of treatment with dapagliflozin tablets or placebo
Method of measurement
Using liver fibroscan

Secondary outcomes

1

Description
Measurement of CBC/diff
Timepoint
At the beginning of the study and 3 months after the start of treatment
Method of measurement
Using laboratory methods

2

Description
Measurement of ALT,
Timepoint
At the beginning of the study and 3 months after the start of treatment
Method of measurement
Using laboratory methods

3

Description
Measurement of AST
Timepoint
At the beginning of the study and 3 months after the start of treatment
Method of measurement
Using laboratory methods

4

Description
Measurement of HDL
Timepoint
At the beginning of the study and 3 months after the start of treatment
Method of measurement
Using laboratory methods

5

Description
Measurement of LDL
Timepoint
At the beginning of the study and 3 months after the start of treatment
Method of measurement
Using laboratory methods

6

Description
Measurement of TG
Timepoint
At the beginning of the study and 3 months after the start of treatment
Method of measurement
Using laboratory methods

7

Description
measuremnet of Chol
Timepoint
At the beginning of the study and 3 months after the start of treatment
Method of measurement
Using laboratory methods

8

Description
measurement of FBS
Timepoint
At the beginning of the study and 3 months after the start of treatment
Method of measurement
Using laboratory methods

9

Description
measurement of Controlled attenuation parameter
Timepoint
At the beginning of the study and 3 months after the start of treatment
Method of measurement
Using liver fibroscan

Intervention groups

1

Description
Intervention group: Intervention group: they will receive the drug Dapagliflozin 10 mg daily for 90 days, produced by Medava Pharmaceutical Company, Tehran, Iran.
Category
Treatment - Drugs

2

Description
Control group: They will receive the placebo, which is similar in appearance to the pills of the intervention group, for 90 days, produced by Medava Pharmaceutical Company, Tehran, Iran.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Outpatient clinic of endocrinological and metabolic diseases, Qaim Hospital, Mashhad, Iran

Full name of responsible person
Zahra Mazloum Khorasani

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Ahmedabad St.-Qaim Hospital

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99199-91766

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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https://mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Zahra Mazloum Khorasani

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Ahmad abad street, Qaim hospital

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Person responsible for updating data

Contact

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Mashhad University of Medical Sciences

Full name of responsible person

Majid Nabizadeh Marvast

Position

endocrinology and metabolism clinical fellow

Latest degree

Specialist

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

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