

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Investigating the effects of empagliflozin and dapagliflozin in patients recently undergone liver transplantation: A randomized double-blind placebo controlled trial

Protocol summary

Study aim

Investigating the effects of empagliflozin and dapagliflozin in patients recently undergone liver transplantation

Design

150 patients will be randomly assigned to three groups (50 each) using systematic randomization. Their demographic and clinical data will be assessed, and they will receive empagliflozin 10 mg, dapagliflozin 10 mg, or a placebo for six months while continuing standard treatment. Data will be collected via patient records and bedside interviews.

Settings and conduct

After the selection of samples, none of the participants will be informed about the randomization process or group allocation. The empagliflozin, dapagliflozin, and their respective placebos will be identical in shape, color, and size and will be provided to patients in identical packaging. Patients assessments will be conducted at baseline, weekly for the first two months, and biweekly thereafter until the fourth month.

Participants/Inclusion and exclusion criteria

This pilot study will be conducted on 150 participants aged 18 to 80 years who have undergone liver transplantation and have provided written informed consent. Patients with a history of empagliflozin or dapagliflozin use, renal failure with an eGFR <30 mL/min/1.73 m², hepatic failure with a Child-Pugh score of C, pre-existing type 2 diabetes mellitus, inflammatory or autoimmune diseases, malignancy, pregnancy, lactation, symptomatic hypotension, systolic blood pressure below 100 mmHg or above 180 mmHg, or contraindications to empagliflozin or dapagliflozin will be excluded from the study.

Intervention groups

patients recently undergone liver transplantation

Main outcome variables

Investigating and comparing the effectiveness of empagliflozin and dapagliflozin on the occurrence of new diabetes mellitus; protective effects of empagliflozin and dapagliflozin on CNI drugs in liver transplant patients compared to placebo

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170609034406N14**

Registration date: **2025-12-05, 1404/09/14**

Registration timing: **retrospective**

Last update: **2025-12-05, 1404/09/14**

Update count: **0**

Registration date

2025-12-05, 1404/09/14

Registrant information

Name

Afshin Gharekhani

Name of organization / entity

Faculty of Pharmacy/Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 1315

Email address

gharekhanian@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-21, 1404/02/31

Expected recruitment end date

2025-11-21, 1404/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of empagliflozin and dapagliflozin in patients recently undergone liver transplantation: A randomized double-blind placebo controlled trial

Public title

Empagliflozin and dapagliflozin in liver transplantation

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with liver transplantation aged 18 to 80
consented patients

Exclusion criteria:

Pregnancy Lactation kidney failure heart failure
contraindications of empagliflozin or dapagliflozin
systolic blood pressure less than 100 or more than 180
mm Hg Autoinflammatory diseases Malignancy Diabetes
mellitus

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be carried out using random
allocation site
(<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) by blocked randomization method with random
block size 6 and 9.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and health care providers are not aware of
the type of grouping of patients, and the study drug will
be unrecognizable to patients and related treatment
staff. A matched placebo is identical to colchicine in
every aspect, such as appearance, smell, and taste. The
only person who will know the type of drug is the
coordinator of the study

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tabriz University of Medical
Sciences

Street address

Research & Technology Dept, Central Building No. 2,
Third Floor, Tabriz University of Medical Sciences,
Golghast St, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2025-03-03, 1403/12/13

Ethics committee reference number

IR.TBZMED.REC.1403.1048

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

liver transplantation

ICD-10 code

Z94.4

ICD-10 code description

Liver transplant status

Primary outcomes**1****Description**

acute organ rejection

Timepoint

before intervention, second week, 4th week, 8th week,
12th week and 16th week after intervention

Method of measurement

biopsy

2**Description**

survival of transplanted tissue

Timepoint

at baseline, the third month and the sixth month after
the intervention

Method of measurement

clinical assessment

Secondary outcomes

1

Description

Effect of empagliflozin and dapagliflozin on the incidence of new diabetes mellitus following liver transplantation

Timepoint

at baseline, the third month and the sixth month after the intervention

Method of measurement

Measurement of hemoglobin A1C, fasting blood sugar and two-hour blood sugar

Intervention groups

1

Description

Intervention group: Intervention group: Patients will receive 10mg (Gloripa) of empagliflozin oral once daily for six months with standard treatments

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: Patients will receive 10mg of dapagliflozin (gloxiga) oral once daily for six months with standard treatments.

Category

Treatment - Drugs

3

Description

Control group: Patients will receive placebo daily for six months with standard treatments

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Transplant Center of Tabriz

Full name of responsible person

Dr Afshin Gharekhani

Street address

Imam Reza Transplant Center of Tabriz, Parastar street

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Postal code

5166614766

Phone

+98 914 103 2283

Email

anqarekhani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Khosro Adibkia

Street address

Tabriz, Daneshghah Street, Golgasht

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335710

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adibkia@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Afshin Gharekhani

Position

Associated professor of Clinical pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of the data of an article can be published after making patients unrecognized.

When the data will become available and for how long

After publishing of article until 6 months after publishing of the results

To whom data/document is available

Data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Researchers that request data will be permitted only to doing analysis according to ethics for scientific aims.

From where data/document is obtainable

Applicants can receive data by sending an E-mail to address of anqarekhani@yahoo.com and get response from Dr. Afshin Gharekhani

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

After contacting with corresponding author (Dr. Afshin Gharekhani), data will be sent to Tabriz Imam Reza hospital ethics committee and after receiving permission, data will be sent to applicants

Comments