

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Efficacy and Safety of Empagliflozin in patients with Metabolic Associated Steatotic Liver Disease: a randomized controlled trial

Protocol summary

Study aim

To assess the Efficacy and Safety of Empagliflozin in patients with Metabolic Associated Steatotic Liver Disease.

Design

The study was a phase 4, single-center, single-blinded, randomized controlled trial. It enrolled a total of 46 participants.

Settings and conduct

Conducted at the Department of Medicine and Gastroenterology, Mayo Hospital Lahore. Identical placebo tablets matching empagliflozin 10 mg in size, shape, color, and packaging will be used to maintain blinding integrity. All medications will be dispensed in coded, identical blister packs labeled without revealing treatment allocation. All participants will receive standardized instructions for medication intake and possibility of mild side effects to avoid differentiating between groups and perception bias.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients having age between 30-65 years, both male and female, having -MASLD receiving Empagliflozin therapy after giving consent along with standard therapy. Exclusion criteria: Patients having HCV, HBV, those having tumor of liver. Patients that are unable to understand local languages. Non cooperative patients, critical cases (ICU admitted, mechanical ventilation, coma patient, GCS score less than 10) are excluded from the study.

Intervention groups

Patients will be randomly administered with empagliflozin 10 mg once daily orally for six months without modifying existing treatment for MASLD. The placebo/control group in the empagliflozin study received standard MASLD therapy along with a daily oral placebo tablet identical in appearance to empagliflozin.

Main outcome variables

Efficacy of Empagliflozin: Measured by the Fibrosis-4 (FIB-4) Index score, which assesses liver fibrosis

progression. Safety of Empagliflozin: Assessed through the SF-36 (Short Form-36 Health Survey), which measures the physical and mental health of the patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250430065534N2**

Registration date: **2025-05-13, 1404/02/23**

Registration timing: **prospective**

Last update: **2025-05-13, 1404/02/23**

Update count: **0**

Registration date

2025-05-13, 1404/02/23

Registrant information

Name

Muhammad Rizwan Tariq

Name of organization / entity

Mayo Hospital Lahore

Country

Pakistan

Phone

+92 333 7692728

Email address

ibneislam190@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-06, 1404/03/16

Expected recruitment end date

2025-07-06, 1404/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and Safety of Empagliflozin in patients with Metabolic Associated Steatotic Liver Disease: a randomized controlled trial

Public title

Efficacy and Safety of Empagliflozin in patients with fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients having age between 30-65 years Both male and female Patients having -MASLD receiving Empagliflozin therapy after giving consent, along with standard therapy

Exclusion criteria:

Patients having HCV, HBV, those having tumor of liver Patients that are unable to understand local languages Non cooperative patients Critical cases (ICU admitted, mechanical ventilation, coma patient, GCS score less than 10)

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

1. Method of randomization: Simple randomization. 2. Unit of randomization: Individual patient. 3. Randomization strata in stratified randomization: Not applicable (no stratification used). 4. Tools used in randomization: Computer-generated random numbers and sealed opaque envelopes. 5. How the random sequence was built: Using a computer software to generate a random sequence. 6. Whether or not allocation concealment was carried out: Yes, through sealed, sequentially numbered opaque envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participant will be blind and blinding will be ensured through a rigorous placebo-controlled design. Identical placebo tablets matching empagliflozin 10 mg in size, shape, color, and packaging will be used to maintain blinding integrity. All medications will be dispensed in coded, identical blister packs labeled without revealing treatment allocation. Participants will receive standardized instructions for medication intake to avoid

differentiating between groups. They will also be informed that mild side effects may occur in all participants, regardless of group, to minimize perception bias. Follow-up assessments will be conducted using neutral, standardized language to prevent unblinding.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Institutional review board

Street address

H897+X5V Chowk, Nila Gumbad Rd, Neela Gumbad

City

Lahore

Postal code

54000

Approval date

2025-02-25, 1403/12/07

Ethics committee reference number

186/RC/KEMU

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

MASLD/Metabolic Associated Steatotic Liver Disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

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

Change in liver fibrosis as measured by the FIB-4 Index

Timepoint

After completion of 6 months of treatment

Method of measurement

Pre- and post-intervention FIB-4 scores were used to assess the efficacy of empagliflozin.

Secondary outcomes**1****Description**

Safety and health-related quality of life as measured by the SF-36 Health Survey

Timepoint

After completion of 6 months of treatment

Method of measurement

SF-36 was used to assess both physical and mental health status of participants.

Intervention groups

1

Description

Intervention group: Patients who will be randomly administered with empagliflozin 10 mg once daily orally for six months without modifying existing treatment for MASLD

Category

Treatment - Drugs

2

Description

Control group: Patients will be randomly administered with placebo tablet once daily orally for six months without modifying existing treatment for MASLD

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Department of medicine and gastroenterology, Mayo Hospital Lahore

Full name of responsible person

Dr. Muhammad Umer Sheikh

Street address

Hospital Rd, Anarkali Bazaar

City

Lahore

Postal code

54000

Phone

+92 321 9994005

Email

dr.usheikh@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

King Edward Medical University

Full name of responsible person

Dr. Muhammad Umer Sheikh

Street address

H897+X5V Chowk, Nila Gumbad Rd, Neela Gumbad

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54000

Phone

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Email

dr.usheikh@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

King Edward Medical University

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**

King Edward Medical University

Full name of responsible person

Dr. Muhammad Umer Sheikh

Position

Senior Registrar

Latest degree

Medical doctor

Other areas of specialty/work

Gastroenterology

Street address

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Deidentified Individual Participant Data (IPD): Includes demographic data (age, sex, socioeconomic status),

baseline clinical data (stage of cirrhosis, CLDQ scores), and follow-up outcome data (monthly CLDQ scores for 6 months). Analytic Code: Statistical analysis scripts used to compare outcomes, likely in SPSS or Excel. Study Protocol: Full protocol including objectives, methodology, inclusion/exclusion criteria, interventions, and outcome measures. Consent Form: Template of the informed consent document used in local languages. Data Dictionary: Variable definitions, coding instructions, units, and value ranges. Clinical Study Report (CSR): A structured report summarizing methodology, participant flow, statistical analysis, and results.

When the data will become available and for how long

All data and documents will become available within 6 months after publication of the main study results in a peer-reviewed journal. They will remain available for a minimum of 5 years after the date of publication. Start date (approx.): January 2026 (assuming publication by mid-2025) End date: January 2031 Extensions may be granted upon request, subject to ethical approval and institutional guidelines.

To whom data/document is available

Data and supporting documents will be shared with qualified researchers, healthcare professionals, and academics affiliated with recognized institutions, including universities, hospitals, and nonprofit research organizations. Access for commercial entities (e.g., pharma/biotech companies) may also be considered on a case-by-case basis, provided the intended use is ethically justified and approved by the principal investigator and institutional ethics committee. All requestors will be required to submit a data use agreement, outlining terms for privacy, data security, and non-commercial use unless explicitly approved.

Under which criteria data/document could be used

Access to deidentified IPD and supporting documents will be granted for scientific research purposes only, such as: Secondary analysis to verify study results Meta-analyses or systematic reviews Methodological research or development of new analysis tools Academic research or graduate thesis work Requests must include a brief proposal outlining the research objective, intended use, methodology, and institutional affiliation. All requests will be reviewed by the Principal Investigator (PI) in consultation with the Institutional Ethics Committee. Approval will be based on the scientific merit, ethical soundness, and alignment with patient confidentiality protections.

From where data/document is obtainable

All data and related documents can be requested from: Contact Person: Dr. Muhammad Umer Sheikh Institution: Department of Gastroenterology, Mayo Hospital, Lahore, Pakistan Email: dr.usheikh@gmail.com The data will be shared electronically through secure channels such as institutional file-sharing platforms or password-protected email attachments.

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

Initial Contact: Interested researchers should email a formal request to the Principal Investigator with: A brief research proposal Intended use of the data Institutional

affiliation Ethical approval or justification (if available)
Review Process: The request will be reviewed within 2–4 weeks by the Principal Investigator in collaboration with the institutional ethics committee. Data Use Agreement: If approved, the requester must sign a Data Use Agreement (DUA) that outlines confidentiality, non-

commercial use, and data protection obligations. Data Sharing: Once the DUA is signed, data/documents will be sent electronically within 7–10 working days. This process ensures transparency, patient privacy, and ethical data use, while promoting scientific collaboration.

Comments