Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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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Lahore

Postal code

54000

Phone

+92 321 9994005

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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Postal code

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Person responsible for scientific inquiries

Contact

Name of organization / entity

King Edward Medical University

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Position

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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
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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