Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of standard therapy with and without Vitamin D supplementation in patients of liver cirrhosis

Protocol summary

Study aim
To compare of the effectiveness of standard therapy with and without vitamin D supplementation in patients of Liver Cirrhosis.

Design
Randomized controlled trial

Settings and conduct
OPD of Gastroenterology department, Mayo hospital Lahore. Participants were blinded by using identical ampules, non-revealing labeling and method of injection.

Participants/Inclusion and exclusion criteria
The study will include seventy-two male and female cirrhotic patients aged 30 to 60 years who will provide informed consent and will be receiving standard therapy. Patients with metastatic liver tumors, those unable to understand local languages, non-cooperative individuals, and critically ill cases — including those admitted to the ICU, on mechanical ventilation, in a coma, or with a Glasgow Coma Scale (GCS) score below 10 — will be excluded from the study. Additionally, patients who have received vitamin D treatment within the two months prior to recruitment will also be excluded.

Intervention groups
Patients will be randomly supplemented with monthly single intramuscular dose of 200,000 IU cholecalciferol /vitamin D3 for 6 months (Vitamin D Group), and the second arm will receive a monthly single intramuscular dose of the placebo (ampule containing 1ml of normal saline 0.9%, that will be obtained from our colleagues in pharmacology department, for 6 months (Placebo Group)

Main outcome variables
The Chronic Liver Disease Questionnaire (CLDQ) will be used to measure changes in quality of life. The raw scores of the participants will be transformed into scale scores, and for all scales, higher scores will indicate better functioning or QOL.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250430065534N1**
Registration date: **2025-05-08, 1404/02/18**
Registration timing: **prospective**

Last update: **2025-05-08, 1404/02/18**
Update count: **0**

Registration date
2025-05-08, 1404/02/18

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
2025-05-15, 1404/02/25

Expected recruitment end date
2025-06-15, 1404/03/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of standard therapy with and without Vitamin D supplementation in patients of liver cirrhosis

Public title
Vitamin D in cirrhosis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients having age between 30-60 years both male and female having liver cirrhosis receiving vitamin D supplementation (as per operational definition) along with standard therapy of treatment

Exclusion criteria:
Patients having metastatic tumor of liver. Patients who are unable to understand local languages. Non cooperative patients Critical cases (ICU admitted, mechanical ventilation, coma patient, GCS score less than 10) any patients with prior vitamin D treatment in the previous two months.

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **72**

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
To ensure effective blinding, both the treatment group (receiving 200,000 IU of Vitamin D intramuscularly) and the placebo group (receiving 1 mL of normal saline intramuscularly) will be administered injections from ampoules that are identical in appearance, volume, and packaging. These ampoules will be coded with non-identifiable labels, such as Group A or B, and only the pharmacist or an independent third party, uninvolved in patient care or outcome assessment, will have access to the allocation code. Injections will be delivered using the same needle and syringe type, into the same anatomical site, and with standardized technique to prevent any perceptible differences in administration that might unblind participants. Although the administering staff will be aware of the contents in this single-blinded design, they will be trained to avoid any verbal or non-verbal cues that could influence the patients' perceptions. All post-injection monitoring will be conducted uniformly without disclosing any information that could hint at group allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Institutional review board King Edward Medical University

Street address
King Edward Medical University, Nila Gumbad, New Anarkali

City
Lahore

Postal code
54000

Approval date
2025-02-25, 1403/12/07

Ethics committee reference number
187/RC/KEMU

Health conditions studied

1

Description of health condition studied
Liver cirrhosis

ICD-10 code
K74

ICD-10 code description
Fibrosis and cirrhosis of liver

Primary outcomes

1

Description
Improvement in quality of life and patient-reported outcomes, assessed using the Chronic Liver Disease Questionnaire (CLDQ).

Timepoint
After 6 months of treatment.

Method of measurement
This outcome will be measured by comparing the CLDQ scores (categorized as high or low) between the Vitamin D group and the placebo group.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: These patients will be randomly supplemented with monthly single intramuscular dose of 200,000 IU cholecalciferol /vitamin D3 for 6 months (Vitamin D Group)
Category
Treatment - Drugs

2

Description
Control group: this arm will receive a monthly single intramuscular dose of the placebo (ampule containing 1ml of normal saline 0.9%.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
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
City
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
H897+X5V Chowk, Nila Gumbad Rd, Neela Gumbad
City
Lahore
Province
Punjab
Postal code
54000
Phone
+92 321 9994005
Email
dr.usheikh@gmail.com

Person responsible for scientific 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

H897+X5V Chowk, Nila Gumbad Rd, Neela Gumbad

City
Lahore

Province
Punjab

Postal code
54000

Phone
+92 321 9994005

Email
dr.usheikh@gmail.com

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
Gastroenterology

Street address
H897+X5V Chowk, Nila Gumbad Rd, Neela Gumbad

City
Lahore

Province
Punjab

Postal code
54000

Phone
+92 321 9994005

Email
dr.usheikh@gmail.com

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. 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.

Comments