

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

King Edward Medical University

Full name of responsible person

Dr. Muhammad Umer Sheikh

Position

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Latest degree

Medical doctor

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
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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. 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