

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of vitamin D supplementation on lipid profile among patients with metabolic syndrome

Protocol summary

Study aim

To determine the effect of vitamin D supplementation on serum total cholesterol, triglycerides, low density lipoproteins and high density lipoproteins among patients with metabolic syndrome

Design

Two arm parallel group randomized trial without any blinding in outcome assessment. Randomization sequences would be generated online and concealed using opaque envelopes. There will be a minimum of 74 patients, equally divided into the two groups.

Settings and conduct

This trial would be done in the outdoor medical clinic of Pak Emirate Military Hospital. Patients would be selected by non-convenience probability sampling technique and included in the study subject to provision of consent. They would be randomized into two groups using computer generated sequences. Allocation concealment would be done using opaque envelopes. Patients in the intervention arm would receive a single dose of oral Vitamin D as stated above, in addition to usual care. Those in the control arm would receive the usual standard care only.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients satisfying National Cholesterol Education Program Adult Treatment Panel III criteria for metabolic syndrome Exclusion criteria: Current use of lipid lowering drugs Use of vitamin D supplements in the last 6 months Hypothyroidism Pregnancy Chronic kidney disease stages 3- 5 Cholestasis Nephrotic syndrome

Intervention groups

Patients would be given two doses of oral Vitamin D 200000 IU to be taken orally at weeks 0 and 4, in addition to usual medications. Patients in the control group would not be given Vitamin D supplements. They would just receive their usual medications

Main outcome variables

Changes in serum total cholesterol, triglycerides, high density lipoproteins and low density lipoproteins levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240215061017N1**

Registration date: **2024-04-14, 1403/01/26**

Registration timing: **prospective**

Last update: **2024-04-14, 1403/01/26**

Update count: **0**

Registration date

2024-04-14, 1403/01/26

Registrant information

Name

Abdul Rehman Arshad

Name of organization / entity

National University of Medical Sciences

Country

Pakistan

Phone

+92 345 6746747

Email address

maj.abdulrehman@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-15, 1403/01/27

Expected recruitment end date

2024-07-15, 1403/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of vitamin D supplementation on lipid profile among patients with metabolic syndrome

Public title
Vitamin D supplementation in metabolic syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients satisfying National Cholesterol Education Program Adult Treatment Panel III criteria for metabolic syndrome
Exclusion criteria:
Current use of lipid lowering drugs Use of vitamin D supplements in the last 6 months Hypothyroidism Pregnancy Chronic kidney disease stages 3- 5 Cholestasis Nephrotic syndrome

Age
From **19 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization of individual patients would be done using computer generated sequences, prepared online. For this purpose, we would use the Random Number Generator available on calculator.net website (<http://https://www.calculator.net/random-number-generator.html>). This sequence would be concealed using opaque envelopes.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Pakistan Emirate Military Hospital
Street address
Pak Emirates Military Hospital, The Mall Road
City
Rawalpindi

Postal code
46000
Approval date
2024-02-16, 1402/11/27
Ethics committee reference number
A/28/ERC/594/23

Health conditions studied

1

Description of health condition studied
Metabolic syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Changes in serum total cholesterol
Timepoint
8 weeks after intervention
Method of measurement
Laboratory testing

2

Description
Changes in serum triglycerides
Timepoint
8 weeks after intervention
Method of measurement
Laboratory testing

3

Description
Changes in high density lipoproteins
Timepoint
8 weeks after intervention
Method of measurement
Laboratory testing

4

Description
Changes in low density lipoproteins
Timepoint
8 weeks after intervention
Method of measurement
Laboratory testing

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vitamin D. This would be given in two oral doses of 200000 IU each, to be taken at weeks 0 and 4.

Category

Treatment - Drugs

2

Description

Control group: No Vitamin D

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Pak Emirates Military Hospital

Full name of responsible person

Altaf Hussain

Street address

The Mall Road

City

Rawalpindi

Postal code

46000

Phone

+92 302 5757487

Email

altafafridi981@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pak Emirates Military Hospital

Full name of responsible person

Altaf Hussain

Street address

The Mall Road

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Postal code

46000

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Email

altafafridi981@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pak Emirates Military Hospital

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

Pak Emirates Military Hospital

Full name of responsible person

Altaf Hussain

Position

Postgraduate resident

Latest degree

Bachelor

Other areas of specialty/work

Internal Medicine

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City

Rawalpindi

Province

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Pak Emirates Military Hospital

Full name of responsible person

Altaf Hussain

Position

Postgraduate resident

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Pak Emirates Military Hospital
Full name of responsible person
Altaf Hussain
Position
Postgraduate Resident
Latest degree
Bachelor
Other areas of specialty/work
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altafafridi981@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The results of this research would be published in a peer reviewed medical journal

When the data will become available and for how long

Data would be available from the PI on reasonable request for 2 years after the paper is published

To whom data/document is available

People working in academic institutions only

Under which criteria data/document could be used

For secondary analysis

From where data/document is obtainable

From the PI, on reasonable request

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

availability within 2 weeks of a request via email

Comments