

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

#### City

Rawalpindi

#### Postal code

46000

#### Phone

+92 302 5757487

#### 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

#### Street address

The Mall Road

#### City

Rawalpindi

#### Province

Punjab

#### Postal code

46000

#### Phone

+92 302 5757487

#### Email

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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

Internal Medicine

#### Street address

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Rawalpindi

#### Province

Punjab

#### Postal code

46000

**Phone**

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**Email**

altafafridi981@gmail.com

**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**

Internal Medicine

**Street address**

The Mall Road

**City**

Rawalpindi

**Province**

Punjab

**Postal code**

46000

**Phone**

+92 302 5757487

**Email**

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**