Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Hypothyroidsim Pregnancy Chronic kidney disease stages 3- 5 Cholestatsis 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
altafafridi981@gmail.com

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
The Mall Road
City
Rawalpindi
Province
Punjab
Postal code
46000

Phone
+92 302 5757487
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 publihed
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