

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of vitamin D3 Supplementation on Serum Level of P-selectin and hs-CRP in Patients with Thrombosis, a Randimized Controlled Trial

Protocol summary

Summary

Purpose: According to the latest published data, P-selectin, a tissue adhesion molecule is one of the most sensitive and the specific biomarkers for diagnosis of venous thromboembolism. In addition, data have indicated that there is a significant correlation between vitamin D3 deficiency and the incidence of thromboembolic events. This study was designed to examine the effect of vitamin D3 supplementation on serum levels of P-selectin. Methods: This was a mono-center, prospective, randomized controlled trial conducted in Tehran Heart Center, affiliated with Tehran Medical University. This study was approved in the ethic committee of university. All consented patients with 18 years old and over and with diagnosis of acute deep vein thrombosis (DVT) and pulmonary embolism (PE) were recruited to this study and were randomized into two groups of intervention (n=20) and control(n=20). The exclusion criteria included the presence of any contraindications to use of vitamin D3, uncontrolled autoimmune and inflammatory diseases, pregnancy and any drugs, conditions and diseases that affect the P-selectin levels. Before supplementation of vitamin D3, serum levels of 25-hydroxy vitamin D3 and P-selectin and hs-CRP in each group were obtained. The intervention group was given a single intramuscular injection of 300,000 IU vitamin D3 but the control group was not given. After one month of follow up the serum levels of 25-hydroxy vitamin D3 and P-selectin and hs-CRP will obtain, analyze, and compare with pre-intervention levels.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112068307N1**

Registration date: **2012-06-12, 1391/03/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-06-12, 1391/03/23

Registrant information

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

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tentezarimaleki@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-06-09, 1391/03/20

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vitamin D3 Supplementation on Serum Level of P-selectin and hs-CRP in Patients with Thrombosis, a Randimized Controlled Trial

Public title

Evaluation of vitamin D3 Supplementation on Serum Level of P-selectin and hs-CRP

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria : patients with confirmed thrombosis up to 1 months; patients with 18 years old and over and consented patients. Exclusion criteria: hypercalcemia, nephrolithiasis, Sarcoidosis, vitamin D supplementation, malabsorption syndrome, Severe infection, uncontrolled autoimmune and inflammatory diseases and pregnancy and any drugs, conditions and diseases that affect the P-selectin levels.

Age
From **18 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
Updated, :

Secondary trial Id
Updated, :

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee, Faculty of Pharmacy, Tehran University of Medical Sciences

Street address
16 Azar street

City
Tehran

Postal code

Approval date
2012-01-29, 1390/11/09

Ethics committee reference number
230/6858

2

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences Ethics Committee

Street address
Updated, :

City
Tehran

Postal code

Approval date
2012-08-11, 1391/05/21

Ethics committee reference number
91-02-33-18319-62209

Health conditions studied

1

Description of health condition studied
Thrombosis

ICD-10 code
I82

ICD-10 code description
Other venous embolism and thrombosis

Primary outcomes

1

Description
p-selectin

Timepoint
before and 1 month after intervention

Method of measurement
ELAISA, lab

2

Description
hs-CRP

Timepoint
before and 1 month after intervention

Method of measurement
ELAISA, lab

Secondary outcomes

1

Description
25-hydroxy vitamin D3

Timepoint
before and 1 month after intervention

Method of measurement
Radioimmunoassay

Intervention groups

1

Description

Control group: is not given vitamin D 300000

Category

N/A

2

Description

Intervention: Ampule Vitamin D3 300,000 IU intramuscle every one month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of researsh, TUMS

Full name of responsible person

Dr. Foutohi

Street address

Vice chancellor for researsh

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of researsh, TUMS

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

TUMS

Full name of responsible person

Dr taher Entezari-Maleki

Position

Board of clinical Pharmacy specialty

Other areas of specialty/work

Street address

Faculty of Pharmacy, Department of Clinical Pharmacy.

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Taher Entezari-Maleki

Position

Faculty member

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty