

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)

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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 researsch, TUMS

Full name of responsible person

Dr. Foutohi

Street address

Vice chancellor for researsch

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 researsch, 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

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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