

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of the effect of Thiamine in the prevention of post-thrombotic syndrome in patients with deep vein thrombosis of the lower extremities

Protocol summary

Study aim

Determining the effect of thiamine in preventing the occurrence of post-thrombosis syndrome in patients with lower limb deep vein thrombosis.

Design

This interventional study is a randomized, double-blind clinical trial that includes two parallel intervention and control groups.

Settings and conduct

Patients with deep vein thrombosis of the lower limbs referred to the Vascular Surgery Clinic of Hamedan University of Medical Sciences in 2022-2023 are included in the study. The diagnosis of DVT in these patients is confirmed by radiological criteria and by a radiologist. Then they are randomly entered into the intervention or control group. The patient and the doctor evaluating the symptoms are not aware that which patient belongs to which group

Participants/Inclusion and exclusion criteria

80 patients with physical status (ASA) class I and II in the age range of 18 to 65 years who had the first episode of isolated DVT in the iliofemoral veins within the last 30 days who did not take the anticoagulant medication in the course of the disease. Exclusion criteria of this study include diabetes mellitus type 1 or 2, BMI greater than 35 or less than 19, Villalta score greater than or equal to 5, pregnancy, underlying coagulopathy, active cancer, Autoimmune vascular diseases (vasculitis), an underlying clinical condition that symptoms or signs interfere with Villalta's criteria and life expectancy is less than 6 months.

Intervention groups

Both the intervention and control groups received the standard treatment related to DVT that includes rivaroxaban similarly, but in the intervention group, in addition to the standard treatment, the patients also received 300 mg of thiamine daily.

Main outcome variables

Evaluation of the patient's score according to the

Villalta index in months 3 and 6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221106056416N1**

Registration date: **2022-12-29, 1401/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-29, 1401/10/08**

Update count: **0**

Registration date

2022-12-29, 1401/10/08

Registrant information

Name

Maziar Bazrafshan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3826 9335

Email address

m.bazrafshan@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Thiamine in the prevention of post-thrombotic syndrome in patients with deep vein thrombosis of the lower extremities

Public title

Evaluation of the effect of Thiamine in the prevention of post-thrombotic syndrome in patients with deep vein thrombosis of the lower extremities

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients Have had a first episode of isolated DVT in the iliofemoral veins within 30 days and have not taken anticoagulant therapy previously Physical status (ASA) class I and II

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The initial selection of the samples is based on the eligibility criteria for entering the study. Still, the allocation of the groups to the standard treatment and the new treatment will be randomized by the method of randomization in a block of 4 and in such a way that the distribution of people will be based on Gender and age groups in two groups of standard treatment and new treatment should be homogeneous. In this method, we use blocks of 4 (double the number of study groups) with different sequences such as AABB, ABAB, etc. until the sample size is reached. The order of placement of groups in a block cannot be guessed. Everyone who enters the study will receive the chosen type of intervention (placebo or thiamine) in a randomly selected block. At the end of the study, when all the blocks are used, there will be an equal number of intervention and control samples.

Blinding (investigator's opinion)

Single blinded

Blinding description

After confirming the patient's entry into the study and initial examination by the specialist, the patient is randomly assigned to one of the intervention or control groups, and the appropriate medicine is given to the patient by the supervisor without the knowledge of the evaluating specialist. The patient himself has been informed in advance that he may receive the new drug

or a placebo, but which one he received will not be determined.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Fahmideh Blvd., Hamedan university of medical science

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2022-10-22, 1401/07/30

Ethics committee reference number

IR.UMSHA.REC.1401.622

Health conditions studied

1

Description of health condition studied

post thrombotic syndrome

ICD-10 code

I87.0

ICD-10 code description

Postthrombotic syndrome

Primary outcomes

1

Description

The amount of Villalta index score in patients with DVT in the third and sixth months after starting treatment with thiamine 300 mg daily

Timepoint

at The end of the third month and at the end of the sixth month after starting the treatment

Method of measurement

Clinical examination by a specialist based on the Villalta index

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group: Receive 300 mg thiamine tablets daily in addition to standard DVT treatment

Category

Treatment - Drugs

2

Description

Control group: receiving placebo in addition to standard DVT treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Mazyar Bazrafshan

Street address

Beheshti Blvd

City

Hamedan

Province

Hamadan

Postal code

6514845411

Phone

+98 81 3264 0020

Email

Besat@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

Street address

Fahmide Blvd, Hamedan university of medical science

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

+98 81 3131 0000

Email

Info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Sciences

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

Hamedan University of Medical Sciences

Full name of responsible person

Mazyar Bazrafshan

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Besat hospital

City

Hamedan

Province

Hamadan

Postal code

6514845411

Phone

+98 81 3826 9335

Fax

Email

m.bazrafshan@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mazyar Bazrafshan

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Phone

+98 81 3826 9335

Fax**Email**

m.bazrafshan@umsha.ac.ir

6514845411

Phone

+98 81 3826 9335

Fax**Email**

m.bazrafshan@umsha.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data are publishable after the de-identification of participants.

When the data will become available and for how long

3 months after publication

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

There is no prohibition

From where data/document is obtainable

M.bazrafshan@umsha.ac.ir

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

The data will be sent to the eligible applicant as soon as possible and within 2 weeks of the correspondence.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Maziar Bazrafshan

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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