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 Villaletta 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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Maziar Bazrafshan
Position
Assistant professor
Latest degree
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Person responsible for updating data

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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