

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Study of the effects of Rosuvastatin in the treatment of patients with acute deep vein thrombosis(DVT) of lower extremities

Protocol summary

Study aim

The effect of using rosuvastatin in the treatment of patients with deep vein thrombosis

Design

A non-randomized, parallel group, phase 3 trial with a control group and blinded outcome assessment. The sample size is 50 patients in each group.

Settings and conduct

This clinical trial study will conduct on DVT patients in Shohada Tajrish, Shahid Modares, and Shahid Labafinejad hospitals. After confirmation of DVT diagnosis, explaining the research goals and duration, and obtaining written consent patients will be enrolled in the study. The evaluators won't inform about the results of the study and group classification. In this study, patients will be treated with Warfarin, Warfarin + Rosuvastatin, rivaroxaban, and Rivaroxaban + Rosuvastatin, respectively. The duration of the study will be 3 months. After the completion of the study, the serum CRP, D-dimer level, the extent of the difference in the size of the lower extremity, as well as the prevalence of PPS will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients older than 18 years of age
Exclusion criteria: Patients with ESRD and patients with CRF who had a GFR below 1.73 mL/min/1.73 m². Patients who need any invasive intervention for treatment of DVT
Patients with active malignancy. Any medical conditions which can interfere with the serum level of CRP and D-dimer. Previous use of statins. Presence of any statin contraindications
Bilateral lower limb DVT

Intervention groups

1-Warfarin 2-Warfarin + Rosuvastatin 3- Rivaroxaban 4- Rivaroxaban + Rosuvastatin

Main outcome variables

Primary outcome: Prevalence of Post thrombotic Phlebitis Syndrome
Secondary Outcome: Serum CRP and D-dimer levels before and after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150621022852N4**

Registration date: **2019-02-27, 1397/12/08**

Registration timing: **retrospective**

Last update: **2019-02-27, 1397/12/08**

Update count: **0**

Registration date

2019-02-27, 1397/12/08

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44429613

Email address

dr.s.asaadi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

2017-09-25, 1396/07/03

Actual recruitment end date

2018-09-20, 1397/06/29

Trial completion date

2019-01-21, 1397/11/01

Scientific title

Study of the effects of Rosuvastatin in the treatment of

patients with acute deep vein thrombosis(DVT) of lower extremities

Public title

Evaluation of the effects of Rosuvastatin in the treatment of patients with deep vein thrombosis(DVT)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with unilateral Deep Vein thrombosis of the lower extremities.

Exclusion criteria:

Patients with ESRD who underwent regular dialysis and patients with CRF who had GFR below 1.73 mL / min. Patients need any invasive intervention in the treatment of DVT. The patient with any illness, including infection and sepsis, which can interfere with the level of inflammatory factors and D-dimer. Patients with history of active malignancy. Bilateral lower limb DVT

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

This blindness study was conducted on clinical outcomes evaluators. Clinical outcomes evaluated only patients at the end of the study and did not play any role in initiating and tracking patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 SBUM, Arabi Ave, Daneshjoo

Blvd, Velenjak,

City

Teharn

Province

Tehran

Postal code

19839-63113

Approval date

2017-12-19, 1396/09/28

Ethics committee reference number

IR.SBMU.REC.1396.651

Health conditions studied

1

Description of health condition studied

Deep Vein Thrombosis

ICD-10 code

I80.2

ICD-10 code description

Phlebitis and thrombophlebitis of other deep vessels of lower extremities

Primary outcomes

1

Description

The incidence of post thrombotic phlebitis syndrome

Timepoint

After three months from the start of the study

Method of measurement

Based on clinical criteria according to Brandjes questionnaire

Secondary outcomes

1

Description

Serum levels of C-reactive protein, D-Dimer, as well as lower limb size

Timepoint

At the end of the third month of study

Method of measurement

Using serum samples to measure serum CRP and D-dimer levels, as well as instrumentation for measuring lower limb size.

Intervention groups

1

Description

Control group: Patients are being treated with warfarin. Drug daily intake of 5 to 10 mg with the goal of maintaining an INR level of 2-3.

Category

Prevention

2

Description

Intervention group: Rivaroxaban group. The dose was 15 mg daily BD daily and then 20 mg daily for the first 3 weeks.

Category

Prevention

3

Description

Intervention group: Warfarin + Resostatin. Warfarin usage similar to the control group plus 20 mg of rosuvastatin daily

Category

Prevention

4

Description

Intervention group: Rivaroxaban + Rosuvastatin. The rivaroxaban dose was 15 mg daily BD daily, followed by 20 mg daily, plus daily 20 mg of rosuvastatin.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-e-tajrish hospital

Full name of responsible person

Dr. Mehdi Pishgahi

Street address

Tajrish sq.Valiasr st

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2

Recruitment center

Name of recruitment center

Shahid Modares Hospital

Full name of responsible person

Dr. Mahdi Pishgahi

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Saadat Abad,Kaj Sq, Shahid Modares Hospital

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Phone

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3

Recruitment center

Name of recruitment center

Shahid labafinejad Hospital

Full name of responsible person

Dr. Mehdi Pishgahi

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Pasdaran st, 9 th Boustan

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lamc@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

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info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Mehdi Pishgahi

Position

Assistance Professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Sina Asaadi

Position

Resident

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Medical doctor

Other areas of specialty/work

General Surgery

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Email

dr.s.asaadi@sbm.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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Yes - There is 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 information about the outcome of the study, will be available after concealment.

When the data will become available and for how long

One year after the publication of the study results

To whom data/document is available

Researchers and university students of related fields can access the data after passing the administrative process.

Under which criteria data/document could be used

A study observer appointed by the ethics committee of Shahid Beheshti University of Medical Sciences can request to receive data after being unidentifiable in order to control the ethical aspects of the study.

From where data/document is obtainable

Head of the Center for Development of Clinical Research - Management of Shohada Tajrish Hospital

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

To receive data, please contact the Shohada Tajrish Hospital Clinical Development Center. After obtaining permission from the Head of the Research Center and

then the Shohada Tajrish Hospital, access to patient

information and study will be provided.
Comments