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 m2/mL / min. 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 m2.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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1989934148
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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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1998734383
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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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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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

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Tehran

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dr.s.asaadi@sbmu.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 HospitalClinical 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