

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The assessment of effect of Rosuvastatin use on reduce of inflammatory markers in patients with venous thromboembolism

Protocol summary

Study aim

The assessment of effect of Rosuvastatin use on reduce of inflammatory markers including neutrophil to lymphocyte ratio, platelet to lymphocyte ratio, mean platelet volume and di-dimer in patients with venous thromboembolism

Design

Two arm parallel group randomised trial with blinded postoperative care; phase 3. 220 patients are enrolled. Intervention group will receive standard treatment of vein thromboembolism and rosuvastatin (10 mg) for 3 months.

Settings and conduct

Both study groups (intervention and control) received anticoagulant therapy. In the intervention group, in addition, they receive rosuvastatin, 10 mg daily for 3 months. Peripheral blood samples are taken to evaluate neutrophil to lymphocyte ratio, platelet to lymphocyte ratio, mean platelet volume and Di-dimer before treatment and 3 months later.

Participants/Inclusion and exclusion criteria

Patients diagnosed with venous thromboembolism, including deep vein thrombosis and pulmonary embolism without a history of inflammatory diseases such as rheumatic diseases, a history of blood diseases affecting neutrophils, lymphocytes and platelets, a history of regular use of anticoagulants or partial anticoagulant use in recent year, history of statin use, history of heart failure, history of liver disease, history of coagulopathy, previous history of venous thromboembolism, history of cancer and kidney patients undergoing dialysis

Intervention groups

Patients will managed according to the standard treatment for vein thromboembolism. Intervention group will receive standard treatment for vein thromboembolism and rosuvastatin for 3 months. Control group will receive standard treatment for vein thromboembolism alone. All patients will followed-up in the outpatient clinic for 3 months.

Main outcome variables

Inflammatory complications of thrombotic disease such as post-thrombotic syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210416050990N1**
Registration date: **2021-04-24, 1400/02/04**
Registration timing: **prospective**

Last update: **2021-04-24, 1400/02/04**

Update count: **0**

Registration date

2021-04-24, 1400/02/04

Registrant information

Name

Toktam Alirezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 2188

Email address

alirezaei.toktam@sbtmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-26, 1400/02/06

Expected recruitment end date

2021-05-25, 1400/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of effect of Rosuvastatin use on reduce of inflammatory markers in patients with venous thromboembolism

Public title

The assessment of effect of Rosuvastatin use in venous thromboembolism

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with venous thromboembolism In the age range of 20-75 years

Exclusion criteria:

History of inflammatory disease such as antiphospholipid syndrom History of hematologic disorders that influence on lymphocyte, neutrophil and platetet History of regular use of anticoagulant drugs (valvular heart disease..) or use of anticoagulant in recent one year Use of statins or fibrate or ezetymab History of heart failure history of coagulopathy History of vein thromboembolism History of cancer Kidney disease under dialysis Liver disease

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **220**

Randomization (investigator's opinion)

Randomized

Randomization description

Recruited patients are randomly allocated to either intervention or control arm. Both arms are in equal size. Randomization sequence is generated by Random Allocation Software version 1.0 May 2004, using a simple random method. It generates a randomization code for each participant (individual randomization). Randomization is run just one time at the beginning of the study. Then participants' crossover based on the first randomized allocation. Sequentially numbered sealed opaque envelopes are used to conceal the allocation. Each participant receives one envelope containing the randomization code.

Blinding (investigator's opinion)

Not blinded

Blinding description**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

Tajrish square, Shohada-e-tajrish hospital

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Postal code

1989934148

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.SBMU.MSP.REC.1398.454

Health conditions studied**1****Description of health condition studied**

Venous thromboembolism includes deep vein thrombosis and pulmonary embolism

ICD-10 code

Code I82

ICD-10 code description

venous embolism and thrombosis

Primary outcomes**1****Description**

Reduce in inflammatory markers

Timepoint

At the moment of start of treatment and 3 months later

Method of measurement

Peripheral blood sample

Secondary outcomes**1****Description**

Reduce of inflammation

Timepoint

3 months later

Method of measurement

Blood sample

Intervention groups

1

Description

Intervention group: In addition to the standard treatment of venous thromboembolism, from the first day of treatment, they receive rosuvastatin 10 mg dose from Dr. Abidi company, one tablet daily for 3 months

Category

Treatment - Drugs

2

Description

Control group: They receive standard treatment for venous thromboembolism (anticoagulants only)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti University hospitals

Full name of responsible person

Hanieh Sattari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Grant name

Grant code / Reference number

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

No

Title of funding source

-

Proportion provided by this source

1

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

Toktam Alirezaei

Position

Associate professor

Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available