Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Feb 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
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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 envelops 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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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
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Sponsors / Funding sources

1

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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
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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