Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Efficacy and safety of rivaroxaban versus enoxaparin on treatment of radial artery thrombosis after coronary arteries angiography

Protocol summary

Study aim
Comparison the efficacy and safety of enoxaparin versus rivaroxaban in radial artery thrombosis after coronary artery angiography

Design
Two arm parallel group randomized trial on 40 patients. Randomization will be performed via rand function of Excel.

Settings and conduct
The trial will be held in a hospital setting (Rajaie Cardiovascular Medical and Research center, Tehran) on patients with radial artery thrombosis after coronary angiography. Patients will be randomized via central web based method into two interventional groups with two different anticoagulation regimen. Treating physician and patients will not be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Provision of signed and dated informed consent form; All the patients that diagnosed with radial artery thrombosis after coronary angiography; Men and Women; age ≥ 18 year-old. Exclusion criteria: Patients undergoing percutaneous coronary intervention; A condition associated with a high risk of bleeding; Severe renal dysfunction (creatinine clearance <30 mL/min); being allergic to Rivaroxaban/Enoxaparin

Intervention groups
In this study there are two interventional groups: first group: patients will receive rivaroxaban. Second group: patients will receive enoxaparin.

Main outcome variables
Radial artery recanalization, Bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200111046084N1**
Registration date: **2020-05-15, 1399/02/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-15, 1399/02/26**
Update count: **0**

Registration date
2020-05-15, 1399/02/26

Registrant information
Name
Mohsen Maadani
Name of organization / entity
Rajaie Cardiovascular Medical, and Research Center
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Iran (Islamic Republic of)
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mohsenmaadani1343@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2020-05-21, 1399/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy and safety of rivaroxaban versus enoxaparin on treatment of radial artery thrombosis after coronary arteries angiography

Public title
Effect of rivaroxaban in radial artery thrombosis

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Provision of signed and dated informed consent form All the patients that diagnosed with radial artery thrombosis after coronary angiography Men and Women being at the age of 18 years old or over
Exclusion criteria:
Patients undergoing percutaneous coronary intervention A condition associated with a high risk of bleeding Severe renal dysfunction (creatinine clearance <30 mL/min) Being allergic to rivaroxaban/enoxaparin
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed via permuted block randomization method. Allocation will be generated via a web based system and consequently concealment will be central using computer software. Unit of randomization will be individual patients and no stratification will be applied.
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
Ethic committee of Rajaie Cardiovascular Medical and Research Center
Street address
Hashemi Rafsanjani highway; Vali-Asr street
City
Tehran
Province
Tehran
Postal code
1995614331
Approval date
2018-06-30, 1397/04/09
Ethics committee reference number
IR.RHC.REC.1397.020

Health conditions studied

1

Description of health condition studied
Radial artery thrombosis
ICD-10 code
I74.2
ICD-10 code description
Embolism and thrombosis of arteries of the upper extremities

Primary outcomes

1

Description
Radial artery recanalization
Timepoint
4 weeks after start of treatment with rivaroxaban or enoxaparin
Method of measurement
Doppler Ultrasound

Secondary outcomes

1

Description
Bleeding
Timepoint
During 4 weeks of treatment with rivaroxaban or enoxaparin
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Rivaroxaban 20 mg oral tablet , patents will receive rivaroxaban 20 mg daily for 4 weeks after diagnosis of radial artery thrombosis
Category
Treatment - Drugs

2

Description
Control group: Enoxaparin vial, 1 mg/kg subcutaneous daily for 4 weeks after diagnosis of radial artery thrombosis
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rajaie Cardiovascular Medical and Research Center
Full name of responsible person
Mohsen Maadani
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rajaie Cardiovascular Medical and Research Center
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Feridoun Nouhi
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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
Rajaie Cardiovascular Medical and Research Center

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
Rajaie Cardiovascular Medical and Research Center
Full name of responsible person
Parham Sadeghipour
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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