

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

Registration timing: **registered_while_recruiting**

Study aim

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

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

Update count: **0**

Registration date

2020-05-15, 1399/02/26

Design

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

Registrant information

Name

Mohsen Maadani

Name of organization / entity

Rajaie Cardiovascular Medical, and Research Center

Country

Iran (Islamic Republic of)

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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.

Recruitment status

Recruitment complete

Funding source

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 \geq 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

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2020-05-21, 1399/03/01

Intervention groups

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

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Radial artery recanalization, Bleeding

Trial completion date

empty

General information

Scientific title

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

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200111046084N1**

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

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

Full name of responsible person

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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Position

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Person responsible for updating data

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Latest degree

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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