

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of the efficacy and side effects of anti platelets in comparison with anti coagulation in coronary artery ectasia patients

Protocol summary

Study aim

Evaluation of the efficacy and side effects of antiplatelet and anticoagulant therapy in patients with coronary artery ectasia.

Design

A Clinical trial with control group, parallel groups, single blinded, randomized, phase 2-3 on 148 patients.

Settings and conduct

Patients who were diagnosed with coronary artery ectasia after performing angiography at Ayatollah Mousavi Hospital in Zanjan are examined. We classify patients who need stenting in one category and patients who do not need stenting in another. Then the patients in the first group (stenting) were randomly divided into two groups and for one group prescribed a combination of two antiplatelet drugs (DAPT) and one anticoagulant drug and for the other group only two We prescribe antiplatelet drug (DAPT). Also, in the second group (non-stenting) are randomly divided into two categories. For the first group of these patients we prescribed two anti platelet drugs and for the second group we prescribed an anti platelet and an anticoagulant drug. In this study, rivaroxaban 2.5 mg twice daily was used as an anticoagulant, aspirin 80 mg daily, and clopidogrel 75 mg daily as an antiplatelet drug. The analyzer is not aware of the drugs used in each group and study groups are provided to them in a coded form.

Participants/Inclusion and exclusion criteria

Coronary artery ectasia , renal failure and hepatic failure , history of taking anticoagulants.

Intervention groups

When comparing the use of two anti platelet drugs (DAPT) and one anticoagulant drug with only two anti platelet drugs in patients with coronary artery ectasia requiring stent. When comparing the use of two anti platelet drugs with one anti platelet drug and one anticoagulant drug in patients with coronary artery ectasia without stent.

Main outcome variables

Myocardial infarction, hemorrhagic stroke, mortality, major and minor bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210110049984N1**

Registration date: **2021-10-25, 1400/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-25, 1400/08/03**

Update count: **0**

Registration date

2021-10-25, 1400/08/03

Registrant information

Name

Behnoosh Poorkarimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 0001

Email address

Info.behnoosh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-19, 1400/06/28

Expected recruitment end date

2022-06-18, 1401/03/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and side effects of anti platelets in comparison with anti coagulation in coronary artery ectasia patients

Public title

Efficacy and side effects of antiplatelets with anticoagulants in Coronary Artery Ectasia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Ectatic coronary artery in angiography

Exclusion criteria:

History of taking anticoagulant drug Coagulation disorder
Hepatic failure Renal failure

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **148**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method in this study is a simple randomization which also uses individual units. Individuals in this study are divided into 4 groups without special bias.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study groups are coded however the analyzer is not aware of the drugs used in each group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of zanjan University of Medical Sciences

Street address

No. 128, Negin street, opposite the intersection of

Negin North, Negin town

City

Zanjan

Province

Zanjan

Postal code

۴۵۱۴۹۹۴۴۱۳

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.ZUMS.REC.1400.238

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

Ectatic coronary artery

ICD-10 code

2021 ICD-1

ICD-10 code description

Abnormal balloon- or sac-like dilatation in the wall of coronary vessels. Most coronary aneurysms are due to coronary atherosclerosis, and the rest are due to inflammatory diseases

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

Myocardial infarction

Timepoint

Up to one year from the intake of the medication

Method of measurement

Questionnaire

2**Description**

Stroke

Timepoint

Up to one year from the intake of the medication

Method of measurement

Questionnaire

3**Description**

Mortality

Timepoint

Up to one year from the intake of the medication

Method of measurement

Questionnaire

4**Description**

Major bleeding

Timepoint

Up to one year from the intake of the medication

Method of measurement

Questionnaire

5

Description

Minor bleeding

Timepoint

Up to one year from the intake of the medication

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with coronary artery ectasia who have undergone stenting are treated with aspirin 80 mg daily, clopidogrel 75 mg daily, and rivaroxaban 2.5 mg twice daily for one year.

Category

Treatment - Drugs

2

Description

Intervention group: Patients with non-stenting coronary artery ectasia are treated with aspirin 80 mg daily and rivaroxaban 2.5 mg twice daily for one year.

Category

Treatment - Drugs

3

Description

Control group: Patients with coronary artery ectasia who have undergone stenting are treated with aspirin 80 mg daily and clopidogrel 75 mg daily for one year.

Category

Treatment - Drugs

4

Description

Control group: Patients with non-stenting coronary artery ectasia are treated with aspirin 80 mg daily and clopidogrel 75 mg daily for one year.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital in Zanjan

Full name of responsible person

Behnoush pourkarimi fatideh

Street address

No. 128, Negin street, opposite the intersection of Negin North, Negin town

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زنجان

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Postal code

4514994413

Phone

+98 24 3313 0001

Email

info.behnoosh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Behnoush pourkarimi fatideh

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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

Personal

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Behnoush pourkarimi fatideh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Behnoosh pourkarimi fatideh

Position

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Person responsible for updating data

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Full name of responsible person

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Position

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

After analyzing the data and defending the dissertation,
it will be sent as an article to reputable journals with the
preservation of patients' information for publication.

When the data will become available and for how long

After completing the plan

To whom data/document is available

All individuals, legal, academic, non-academic

Under which criteria data/document could be used

In case of coordination with the responsible person and
written request and with the permission of patients

From where data/document is obtainable

By email to the project manager
info.behnoosh@gmail.com

What processes are involved for a request to access data/document

E-mail or correspondence to the project manager,
inserting personal and organizational details and
specifying the application of the information received will
be answered within a week.

Comments