

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Assesment and compair the prognosis of warfarin and rivaroxaban in patient with open heart surgery and endarterectomy

Protocol summary

Study aim

The goal of this study is to use of rivaroxaban instead of warfarin because of the same effect to reduce the major complication of warfarin in major life threatening bleeding. Although in treatment with rivaroxaban there is not need to routine check for anticoagulant level.

Design

Randomized clinical trial, with parallele group of 60 patients, that treat with warfarin or rivaroxaban

Settings and conduct

The study was done on patients who undergo CABG and coronary endarterectomy in Imam Ali hospital of Kermanshah from 22.11.2018 to 21.3.2019

Participants/Inclusion and exclusion criteria

All patient undergo CABG without prosthetic heart valve and with normal renal function can participate in the study

Intervention groups

Patients who receive warfarin; patients who receive rivaroxaban

Main outcome variables

To substitute rivaroxaban instead of warfarin because of same effect and lesser bleeding complication and easy use for patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181124041746N1**

Registration date: **2019-01-19, 1397/10/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-19, 1397/10/29**

Update count: **0**

Registration date

2019-01-19, 1397/10/29

Registrant information

Name

Delnia Rahimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3837 0252

Email address

dilniya.rahimpour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesment and compair the prognosis of warfarin and rivaroxaban in patient with open heart surgery and endarterectomy

Public title

Effect of warfarin and rivaroxaban in coronary endarterectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing CABG and endarterectomy

Exclusion criteria:

Patients with prosthetic valve ESRD patents

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Kermanshah University of
Medical Sciences

Street address

Shahid Beheshti Blvd., Kermanshah University of
Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-11-14, 1397/08/23

Ethics committee reference number

IR.KUMS.REC.1397.580

Health conditions studied

1

Description of health condition studied

Coronary artery disease

ICD-10 code

I25

ICD-10 code description

Atherosclerotic heart disease

2

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bleeding

Timepoint

3rd day then 3rd month

Method of measurement

Questionnaire-interview

2

Description

Cerebrovascular accident

Timepoint

3rd day and 3rd month

Method of measurement

Questionnaire-interview

3

Description

Cardiovascular complication

Timepoint

3rd day and 3rd month

Method of measurement

Questionnaire-interview

4

Description

Thromboembolism

Timepoint

3rd day and 3rd month

Method of measurement

Questionnaire-interview

Secondary outcomes

empty

Intervention groups

1

Description

In one group, patients receive warfarin (vitamin K antagonist) for 3 months. The dosage of drug was based on patients' INR. Goal INR was 2-3. We check INR frequently to achieve this goal.

Category

Treatment - Drugs

2

Description

In this group, patients without chronic kidney disease were treated with rivaroxaban (anti-Xa factor) 15 mg daily for 3 months. Dosage of rivaroxaban was fixed and there was no need for check of coagulation state.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Imam Ali hospital of Kermanshah

Full name of responsible person

Delnia Rahimpour

Street address

Imam Ali hospital, Shahid beheshti Blvd.

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Alireza Rai

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Alireza_Rai@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences

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**

Kermanshah University of Medical Sciences

Full name of responsible person

Delnia Rahimpour

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**

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resident

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable