

# 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 arthry 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

Questinannair-interview

### 2

#### Description

Cerebrovascular accident

#### Timepoint

3rd day and 3rd month

#### Method of measurement

Quastionnair-interview

### 3

#### Description

Cardiovascular complcation

#### Timepoint

3rd day and 3rd month

#### Method of measurement

Questionnair-interview

### 4

#### Description

Thromboembolism

#### Timepoint

3rd day and 3rd month

#### Method of measurement

Questionnair-interview

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In one group, patients recieve warfarin (vitamink antagonist)for 3 monthThe dosage of drug was baced on patients INR. Goal INR was 2-3.we check INR frequently to acheive this goal

#### Category

Treatment - Drugs

### 2

#### Description

In this group patients without chronic kidney diseasd were treated with rivaroxaban(anti xa factor) 15 mg daily for 3month. Dosage of rivaroxaban was fixed and there was not need for check of coagulation state.

**Category**

Treatment - Drugs

**Recruitment centers****1****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.

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847145

**Phone**

+98 83 3836 0041

**Email**

Dilniya.rahimpour@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Alireza Rai

**Street address**

Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.

**City**

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**Phone**

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**Email**

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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**Email**

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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