

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Early Anti-Coagulation therapy in new onset atrial fibrillation after coronary artery bypass graft operation; Warfarin vs Rivaroxaban for stroke prevention and risk of bleeding assessment: A randomized clinical trial

Protocol summary

Study aim

Comparative effectiveness of Warfarin vs Rivaroxaban for stroke and transient ischemic attack prevention in new onset atrial fibrillation (AF) after coronary artery bypass graft (CABG) operation as a randomized clinical trial and also major bleeding risk assessment in these two groups

Design

Two arm parallel group open-label 1:1 block randomized trial (each group : 795 patients), Phase 3

Settings and conduct

Patients who undergone Isolated CABG in Tehran Heart Center with newly diagnosed post operative AF, enrolled the 2 arm parallel group 1:1 randomized trial. Regardless of CHA2DS2_VASC criteria, one group will receive Rivaroxaban 72 hours after the diagnosis and the other will receive Warfarin after bridge therapy. The therapeutic range of warfarin is INR 2-3. Both of medications will be continued for 4 weeks.

Participants/Inclusion and exclusion criteria

Inclusion:Isolated CABG Two or more episodes of New Onset AF (each lasting > 20 minutes) or persistent atrial fibrillation lasting > 24 hours Exclusion:History of allergy to study drugs History of recent stroke before surgery or post-operation before initiation of study medications At least moderate Mitral or Aortic valve stenosis not repaired or replaced by surgery Recent or ongoing pregnancy Any other indication for anticoagulation therapy (Including DVT, PTE, mechanical valve) Baseline INR > 1.7 History of atrial fibrillation before operation Postoperative bleeding before initiation of anticoagulation medications Glomerular filtration rate(GFR)<30 ml/min

Intervention groups

Warfarin Rivaroxaban

Main outcome variables

Primary outcome: Stroke, Transient Ischemic Attack up to 30 days after discharge Secondary outcome: Major bleeding up to 30 days after discharge

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200304046696N1**

Registration date: **2020-03-18, 1398/12/28**

Registration timing: **prospective**

Last update: **2020-03-18, 1398/12/28**

Update count: **0**

Registration date

2020-03-18, 1398/12/28

Registrant information

Name

Mojgan Ghavami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 9256

Email address

ghavami_mojgan69@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2024-04-03, 1403/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Early Anti-Coagulation therapy in new onset atrial fibrillation after coronary artery bypass graft operation; Warfarin vs Rivaroxaban for stroke prevention and risk of bleeding assessment: A randomized clinical trial

Public title

Early Anti-Coagulation therapy in new onset atrial fibrillation after coronary artery bypass graft operation; Warfarin vs Rivaroxaban for stroke prevention

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who undergone Isolated coronary artery bypass graft in Tehran Heart Center Two or more episodes of New Onset Atrial Fibrillation (each lasting > 20 minutes) or persistent atrial fibrillation lasting > 24 hours

Exclusion criteria:

History of allergy to study drugs History of recent stroke (within 1 month) before surgery or post-operation before initiation of study medications At least moderate Mitral or Aortic valve stenosis not repaired or replaced by surgery Recent (within 1 year) or ongoing pregnancy (Blood pregnancy test (b-HCG level) will be checked for young women at the beginning of the study) Any other indication for anticoagulation therapy (Including DVT, PTE, mechanical valve) Baseline INR > 1.7 History of atrial fibrillation before operation Postoperative bleeding before initiation of anticoagulation medications Glomerular filtration rate(GFR) < 30 ml/min

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **1590**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization using random allocation software, Block size: variable

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 Tehran University of Medical Sciences

Street address

Tehran Heart Center, North Kargar-Ave , Tehran-Iran

City

Tehran

Province

Tehran

Postal code

1411713138

Approval date

2020-01-29, 1398/11/09

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.836

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

Post Operative Atrial Fibrillation

ICD-10 code

I48.0

ICD-10 code description

Paroxysmal atrial fibrillation

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

Stroke or Transient Ischemic Attack (TIA)

Timepoint

Up to 30 days after discharge

Method of measurement

Clinical assessment, Imaging if needed (If neurological examination is favorable for stroke or TIA, the diagnosis will be confirmed by imaging (Brain CT_scan or MRI))

Secondary outcomes**1****Description**

Major Bleeding

Timepoint

Up to 30 days after discharge

Method of measurement

Physical Examination_ Bleeding which requires re-operation or other therapeutic intervention for bleeding assessment (e.g colonoscopy, endoscopy and urologic procedures for hematuria), development of any

intracranial bleeding (Diagnosis will be confirmed by Brain CT_scan or Magnetic resonance Imaging), transfusion > 2 units of blood after drug initiation

Intervention groups

1

Description

Intervention group: Drug Warfarin administration

Category

Treatment - Drugs

2

Description

Intervention group: Drug Rivaroxaban administration

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Mojgan Ghavami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraeian

Street address

Sixth Floor, Vice Chancellor for Research and Technology Departement, Tehran University of Medical Sciences, Qods Ave., Keshavarz Blvd, Tehran, Iran

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

30

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

Tehran University of Medical Sciences

Full name of responsible person

Mojgan Ghavami

Position

Cardiology resident, PhD candidate by research

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Position

Cardiology resident-PhD candidate by research

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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