Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 out come: Stroke, Transient Ischemic Attack up to 30 days after discharge Secondary out come: 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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Tehran Heart Center, North Kargar-Ave , Tehran-Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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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