Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Investigation of the efficacy of dual anti-platelet therapy compared to aspirin on graft patency and peri-operative bleeding in coronary artery bypass graft surgery

Protocol summary

Study aim
superiority of dual anti-platelet therapy(DAPT)(Clopidogrel+Aspirin) compared to mono-therapy(Aspirin) on reduction of early graft occlusion after CABG will be assessed.

Design
In a multi-center, randomized controlled trial with parallel design (phase II) 216 patients will be randomly assigned to intervention(DAPT) or control(aspirin) group.

Settings and conduct
The trial is open-label and will be conducted in three centers for cardiovascular diseases in Tehran, Iran.

Participants/Inclusion and exclusion criteria
Inclusion: Age ≥18 year; Candidate for elective CABG. Exclusion: Concomitant valve surgeries; Concomitant Aortic surgery; Redo-CABG; Not taking Aspirin at least 48 hours before surgery; Clopidogrel use within 5 days before CABG; Any condition with increased bleeding risk that precludes DAPT; Significant bleeding in the first 4 hours after surgery

Intervention groups
Intervention (DAPT): loading dose of 300 mg of Clopidogrel within 24 hours after surgery and a maintenance dose of 75 mg/day for 30 days in combination with 80-325 mg Aspirin Control: Aspirin 80-325 mg/day

Main outcome variables
graft patency evaluated by a CT angiography 6 months after the surgery

General information

Reason for update

Acronym
DAPT in CABG

IRCT registration information
IRCT registration number: **IRCT20171113037434N1**
Registration date: **2018-01-10, 1396/10/20**
Registration timing: **retrospective**

Last update: **2018-01-10, 1396/10/20**
Update count: **0**

Registration date
2018-01-10, 1396/10/20

Registrant information

Name
Seifollah Abdi

Name of organization / entity
Rajaie Cardiovascular Medical and Research Center

Country
Iran (Islamic Republic of)

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+98 21 2392 2356

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dr.abdi@rhc.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2012-05-01, 1391/02/12

Expected recruitment end date
2015-12-30, 1394/10/09

Actual recruitment start date
2012-05-01, 1391/02/12

Actual recruitment end date
2015-12-30, 1394/10/09

Trial completion date
empty

Scientific title
Investigation of the efficacy of dual anti-platelet therapy compared to aspirin on graft patency and peri-operative bleeding in coronary artery bypass graft surgery

Public title
Dual anti-platelet therapy in coronary artery bypass graft surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients Age ≥18 year-old Candidate for elective coronary bypass graft surgery
Exclusion criteria:
1) Concomitant valve surgeries 2) Concomitant Aortic surgery 3) Redo-CABGs 4) Patients who don't take Aspirin at least 48 hours before surgery 5) Clopidogrel use within 5 days before CABG 6) Any condition with increased bleeding risk that precludes dual anti-platelet therapy 7) Significant bleeding in the first 4 hours after surgery
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **216**
Actual sample size reached: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants in this study will be randomized (on a 1: 1 basis) using permuted block method to either dual anti-platelet therapy group (Clopidogrel and Aspirin) or Aspirin monotherapy group within 24 hours after surgery. The process of random assignment will be conducted in our data management center (DMC) a center, located in one of the collaborating hospitals (Rajaie Cardiovascular Medical and Research Center) by the team members do not involve in the conduction of the trial performed. Random sequence will be generated using permuted block randomization method (block of four). After registration of each patient in the trial, the responsible nurse called the center DMC and asked for the assigned study group. According to the random sequence, the staff in the center will announce the assigned group as "Group A" (DAPT) or "Group B" (control) to the nurse.
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 FACULTY OF NURSING AND MIDWIFERY, Karaj Islamic Azad University
Street address
Imam Ali Complex, End of Rajaei-Shahr, Moazen Blvd - Esteghlal Crossroad,
City
Karaj
Province
Alborz
Postal code
3148635731
Approval date
2011-10-31, 1390/08/09
Ethics committee reference number
1390/8/9-29

Health conditions studied

1

Description of health condition studied
coronary artery bypass graft
ICD-10 code
Z95.5
ICD-10 code description
Presence of coronary angioplasty implant and graft

Primary outcomes

1

Description
graft patency
Timepoint
six months after CABG surgery
Method of measurement
coronary CT angiography

Secondary outcomes

1

Description
The amount of chest tube output
Timepoint
four hours after surgery
Method of measurement
Measuring the chest tube drainage (it will be considered significant when its amount is more than 100 cm3 per hour in average for a 4 hours interval in ICU after surgery.)

2

Description

The need for blood transfusions with either of the following:a. ≥ 2 units of packed red blood cells b. ≥ 2 units of fresh frozen plasma c. ≥ 5 units of platelets

Timepoint

hospital stay duration

Method of measurement

Counting the transfused products units

3

Description

In-hospital mortality

Timepoint

hospital stay duration

Method of measurement

observation

Intervention groups

1

Description

Intervention group: Dual anti-platelet therapy (DAPT) group received a loading dose of 300 mg (4 tablets) of Clopidogrel (Plavix ®, Sanofi-Aventis Co.) within 24 hours after surgery and a maintenance dose of 75 mg/day was continued for 30 days in combination with 80-325 mg Aspirin.

Category

Treatment - Drugs

2

Description

Control group: Aspirin 80-325 mg/day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Seyfollah Abdi

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Valiasr Ave Niayesh Intersection

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanofi-Aventis Pharmaceutical Company

Full name of responsible person

Nariman Sadri

Street address

18, 35th Str, Alvand Ave, Argentine Sq.

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1516683511
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Web page address
http://www.sanofi.us/l/us/en/index.jsp
Grant name
Grant code / Reference number
CLOPI_L_05766
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanofi-Aventis Pharmaceutical Company
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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Rajaie Cardiovascular Medical and Research Center
Full name of responsible person
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Associate professor
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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

- study protocol - De-identified Individual Participant Data Set (without patients' name, file number and medical center) - final report of the study

When the data will become available and for how long

After publishing the results of the study

To whom data/document is available

The mentioned data/documents will be available for all the stakeholders. Complementary data can be requested only by academic researchers.

Under which criteria data/document could be used

Written permission from the primary investigator (Dr Abdi) is needed for any publication and usage of data.

From where data/document is obtainable

Documents/ data will be available via contacting Dr Seyfollah Abdi: phone:02123921 or email: dr.abdi@rhc.ac.ir

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

Only process is direct contact with primary investigator.

Comments