

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effect of Dronedarone on prevention of atrial fibrillation after on-pump coronary bypass graft surgery

Protocol summary

Summary

The objective of this study was to assess the effect of Dronedarone on prevention of atrial fibrillation after on-pump coronary bypass graft surgery. Design of study: a randomized, Not blinded study. The study population: patients undergoing coronary artery bypass surgery. Inclusion criteria: Age over 20 years; the first time, On-pump CABG Exclusion criteria: Previous history of AF / AFL; AV block grade 2 and above; Sinus bradycardia with heart rate below 60 bpm; Hemodynamic instability (SBP <100 mmHg); Use of class I or III antiarrhythmia drugs and the other drugs that increase the QT; Uncontrolled heart failure (NYHA class III or IV); Severe liver disease; Valve replacement surgery at the same time; Hypercalemia (K <3.5 mmol / L) or uncontrolled hypermagnesiumemia; Severe renal insufficiency (GFR <10 ml / min); Pregnancy and lactation; Amiodarone injection during CABG Intervention: In first group, using Dronedarone (BD mg 400) two days before and five days after CABG surgery in addition to standard therapy and in second group will receive only standard treatment (carvedilol 6.25 mg BD). Patients in both groups are investigated by incidence of AF, its duration ,CRP levels and drug side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202011965N2**
Registration date: **2012-07-16, 1391/04/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-16, 1391/04/26

Registrant information

Name

Majid Haghjoo

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2163

Email address

majid.haghjoo@gmail.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Dronedarone on prevention of atrial fibrillation after on-pump coronary bypass graft surgery

Public title

Effect of Dronedarone on prevention of atrial fibrillation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age over 20 years; the first time, On-pump CABG Exclusion criteria: Previous history of AF / AFL; AV block grade 2 and above; Sinus bradycardia with heart rate below 60 bpm; Hemodynamic instability (SBP <100 mmHg); Use of class I or III antiarrhythmia drugs

and the other drugs that increase the QT; Uncontrolled heart failure (NYHA class III or IV); Severe liver disease; Valve replacement surgery at the same time; Hypercalemia (K <3.5 mmol / L) or uncontrolled hypermagnesiumia; Severe renal insufficiency (GFR <10 ml / min); Pregnancy and lactation; Amiodarone injection during CABG

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

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 Tehran university of medical science

Street address

ce chancellor for research, Tehran university of medical science

City

Tehran

Postal code

Approval date

2012-07-07, 1391/04/17

Ethics committee reference number

15890

Health conditions studied

1

Description of health condition studied

Atrial Fibrillation

ICD-10 code

I48

ICD-10 code description

Atrial fibrillation and flutter

Primary outcomes

1

Description

The incidence of AF

Timepoint

7 days after intervention

Method of measurement

ECG

2

Description

AF duration

Timepoint

7 days after intervention

Method of measurement

ECG/ In minute

Secondary outcomes

1

Description

CRP level

Timepoint

Daily for 7 days

Method of measurement

Blood sampling, mg/l

2

Description

ICU stay duration

Timepoint

since being admitted to the ICU

Method of measurement

clinical records of patient

3

Description

Hospital stay duration

Timepoint

since being admitted to the hospital

Method of measurement

clinical records of patient

4

Description

mortality

Timepoint

since being admitted to the hospital

Method of measurement

clinical records of patient

5

Description

drug side effects

Timepoint

until adverse drug reaction

Method of measurement

Examination and clinical records of patient

Intervention groups

1

Description

In the control group, only the standard treatment (Beta-blockers) carvedilol 6.25mg BD will be used preoperatively and 5 days after CABG .

Category

Treatment - Drugs

2

Description

In the intervention group, Dronedarone (400 mg BD) will be used preoperatively and 5 days after CABG in addition to standard therapy (using beta-blockers).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Dr. Majid Haghjoo

Street address

Niayesh highway, Vali-Asr Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Fotoohi

Street address

Tehran University of Medical Sciences, Ghods St, Keshavarz Ave

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Cobeldarou

Full name of responsible person

Mr. Memarian

Street address

number 39, Alvand street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Cobeldarou

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Dr. Majid Haghjoo

Position

Research vice chancellor/ Cardiologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Dr. Majid Haghjoo

Position

Research vice chancellor in Rajaie Cardiovascular
Medical and Research Center/ Cardiologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty