

# 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

##### Street address

Niayesh highway, Vali-Asr Ave.

##### City

Tehran

##### Postal code

1996911151

##### Phone

+98 21 2392 2163

**Fax**

**Email**

majid.haghjoo@gmail.com

**Web page address**

## 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**

**Street address**

Niayesh highway, Vali-Asr Ave.

**City**

Tehran

**Postal code**

1996911151

**Phone**

+98 21 2392 2163

**Fax**

**Email**

majid.haghjoo@gmail.com

**Web page address**

## 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*