

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison the effect of preoperative high dose and low dose rosuvastatin therapy on clinical outcomes after coronary artery bypass graft (CABG) surgery

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Effect of high dose and low dose rosuvastatin on outcomes after coronary artery bypass graft (CABG) surgery

Last update: **2018-05-01, 1397/02/11**

Update count: **0**

Registration date

2018-05-01, 1397/02/11

Design

This clinical trial will be conducted on 188 patients who are candidates for elective coronary artery bypass graft surgery. Patients were randomly divided into two equal size groups named group A (5 mg Ropixone) and group B (20 mg Ropixone) using Rand list software and based on quadruple random blocks (block random allocation). Ropixon is given daily from at least two days before surgery through one month after surgery. The study is double blind and the patient and investigator will be blinded. The trial phase is 3.

Registrant information

Name

Mahdieh Sheikhi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

This study will be conducted as a double blind clinical trial in Dr.Heshmat hospital. The patient and investigator will be blinded and randomization will be done based on quadruple random blocks (block random allocation).

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing elective coronary artery bypass graft surgery. Exclusion criteria: Patients with atrial fibrillation, history of myocardial infarction.

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-06-04, 1397/03/14

Intervention groups

1: A; rosuvastatin (Ropixone) tablet 5 mg daily. 2: B; rosuvastatin (Ropixone) tablet 20 mg daily.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Atrial fibrillation; duration of hospitalization; mortality

Trial completion date

empty

General information

Scientific title

Comparison the effect of preoperative high dose and low dose rosuvastatin therapy on clinical outcomes after coronary artery bypass graft (CABG) surgery

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180113038329N1**

Registration date: **2018-05-01, 1397/02/11**

Public title

Effect of rosuvastatin in CABG

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing elective CABG surgery

Exclusion criteria:

Patients with atrial fibrillation (AF) rhythm The current liver disease (illness) including liver Cirrhosis, blood transaminase increment by 3 or more, Blood bilirubin concentration greater than 3 mg / dl Recent use of antifungal medicines (azoles of CYP3A4 inhibitors), Protease inhibitor, Macrolides, Cyclosporine History of myocardial infarction Renal transplantation history Renal insufficiency (serum creatinine> 2.5 mg/dl) Cardiogenic shock Pregnancy Patients with complications during CABG surgery and after that (such as need for surgery for any reason, hemodynamic disorders, long intubation, rhythm disorders, need for shock, need for pericardiocentesis or chest tubing)

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **188**

More than 1 sample in each individual

Number of samples in each individual: **2**

Measuring hs CRP before and after coronary artery bypass graft surgery

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to two groups of 94 people, using the Rand list software. The group A will receive rosuvastatin (Ropixon) 5 mg, the group B will receive rosuvastatin (Ropixon) 20 mg before surgery. Patients will be divided in two groups: A (low dose:5) and B (high dose:20), based on quadruple random blocks (block random allocation).

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind, and the patient and researcher will be blinded, the researcher will not know the dose of the patient's medication. The patient will not be aware of the dose of rosuvastatin. The individuals who are selected as followers during the hospitalization and one month after surgery will be blind. A cardiologist who is not included in the study will done the follow-up of patients without knowing the dose of rosuvastatin.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Research and Technology Deputy, Shahid Siyadati Ave., Namjoo Street

City

Rasht

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Guilan

Postal code

4144666949

Approval date

2017-12-16, 1396/09/25

Ethics committee reference number

IR. GUMS. REC. 1395.368

Health conditions studied

1

Description of health condition studied

Atrial fibrillation

ICD-10 code

I48.0

ICD-10 code description

Paroxysmal atrial fibrillation

Primary outcomes

1

Description

Atrial fibrillation

Timepoint

During the hospitalization period after coronary artery bypass graft surgery and one month later

Method of measurement

Cardiac monitoring, electrocardiogram

2

Description

hospitalization period

Timepoint

Duration of admission after coronary artery bypass graft surgery

Method of measurement

Number of admission days after coronary artery bypass graft surgery

3

Description

Mortality

Timepoint

During the hospitalization period after coronary artery bypass graft surgery and one month later

Method of measurement

Registration of death in the case during hospitalization after coronary artery bypass graft surgery and post-clearance follow up to one month

Secondary outcomes

1

Description

The incidence of myocardial infarction

Timepoint

During the hospitalization period after coronary artery bypass graft surgery until thirty days after that

Method of measurement

Electrocardiogram (ECG), serum cardiac enzymes level by biochemical method

2

Description

Changes of Ejection Fraction (EF)

Timepoint

Before performing coronary bypass graft surgery and thirty days after that

Method of measurement

Determine the percentage of Ejection Fraction (EF) by echocardiography

3

Description

High sensitivity C - Reactive Protein (hs_CRP) level

Timepoint

Before coronary artery bypass graft surgery and three days later

Method of measurement

Blood test, serum high sensitivity C - Reactive Protein (hs_CRP) level by Immunoturbidometry

4

Description

Acute renal failure

Timepoint

Two days after coronary artery bypass graft surgery

Method of measurement

blood test, serum creatinine level by biochemical method

5

Description

Stroke

Timepoint

Duration of hospitalization after coronary artery bypass graft surgery

Method of measurement

Based on patient's clinical symptoms and signs

6

Description

Total cholesterol changes

Timepoint

Before the coronary artery bypass graft surgery and thirty days after that

Method of measurement

blood test, serum total cholesterol level by biochemical method

7

Description

Triglyceride changes

Timepoint

Before the coronary artery bypass graft surgery and thirty days after that

Method of measurement

blood test, serum triglyceride levels by biochemical method

8

Description

Low Density Lipoprotein (LDL) cholesterol changes

Timepoint

Before the coronary artery bypass graft surgery and thirty days after that

Method of measurement

blood test, serum Low Density Lipoprotein (LDL) cholesterol levels by biochemical method

9

Description

High Density Lipoprotein (HDL) Cholesterol changes

Timepoint

Before the coronary artery bypass graft surgery and thirty days after that

Method of measurement

blood test, serum High Density Lipoprotein (HDL) Cholesterol levels by biochemical method

Intervention groups

1

Description

Intervention group 1: rosuvastatin tablet 5 mg once a day, starting at least two days before the coronary artery bypass surgery (CABG) and continuing until one month later.

Category

Treatment - Drugs

2

Description

Intervention group 2: rosuvastatin tablet 20 mg once a

day, starting at least two days before the CABG and continuing until one month later.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Heshmat Rasht Hospital

Full name of responsible person

Mahdieh Sheikhi

Street address

Dr. Heshmat Rasht Hospital, Bayani St., Valiasr Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Shademan Neamati

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

37

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

Other

2

Sponsor

Name of organization / entity

Dr. Abidi Pharmacy Company

Full name of responsible person

Amir Razavian Ardehali

Street address

Dr. Abidi Pharmaceutical Company, Dr. Abidi Blvd, 8th km of Karaj Special Road

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Postal code

76363 - 13897

Phone

+98 21 4454 2499

Fax

Email

info@doctor-abidi.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Dr. Abidi Pharmacy Company

Proportion provided by this source

63

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

Rasht University of Medical Sciences

Full name of responsible person

Sheikhi Mahdieh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Gholipoor Mahboobeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Mahdieh Sheikhi

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the primary and secondary consequences

When the data will become available and for how long

6 to 12 months after printing results

To whom data/document is available

Researchers working in scientific and academic institutions

Under which criteria data/document could be used

Information on the main and secondary outcomes and the method of implementation and analysis and the results after approval by the scientific authority

From where data/document is obtainable

m_sheikhi@gums.ac.ir

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

6 to 12 months after the publication of the results and also after examination by the scientific authority

Comments