

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparing two and seven days antibiotic prophylaxis in prevention of surgical site infection in coronary artery bypass surgery

Protocol summary

Summary

The aim of current study was to compare the efficacy of the two different prophylactic antibiotic regiments (i.e. 2 days vs 7 days period) in prevention of surgical site infection. Current study was done by enrolling 370 patients aged 18-80 years old who underwent the coronary artery bypass surgery. Enrolled Patients were divided into two groups randomly. Randomization was performed by random number generator software (V 1/3). As a double blind study, not only surgeons but also patients weren't aware of the applied regiments, and there was a third person who was responsible for drug prescription in the study. In both groups, before the operation, 2gr of cefazolin was injected intravenously during the induction of anesthesia and continued with dose of 1gr every 6 hours. Then, group 1 received cephalexin capsule (i.e. 500mg) every 6 hours for 5 days, and group 2 (as a placebo group) received placebo every 6 hours for 5 days. Patients were followed for 3 months. Daily care of the wound was done by patients themselves who were trained about the surgical site infection. When they encountered the signs of inflammation (e.g. redness, warmth, pain, and wound secretion) they were referred to doctor. Thereafter the sample of secretion was sent to the laboratory for culture and antibiogram.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707188968N2**

Registration date: **2017-11-08, 1396/08/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-08, 1396/08/17

Registrant information

Name

Mostafa Javanian

Name of organization / entity

Babol University of Medical Sciences-Tropical And Infectious diseases research center

Country

Iran (Islamic Republic of)

Phone

+98 11 1219 0624

Email address

m.javanian@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2017-07-16, 1396/04/25

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing two and seven days antibiotic prophylaxis in prevention of surgical site infection in coronary artery bypass surgery

Public title

Antibiotic prophylaxis in prevention of surgical site infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : All patients with indication of CABG

Exclusion criteria : Patients > 80 and < 18 years old; ejection fraction <35%; history of hypersensitivity to antibiotics; cardiac surgery other than CABG (such as replacing cardiac valves); Presence of infection and recent antibiotic use; immunocompromised patients; repetition of surgery at the same site; Patients on mechanical ventilation more than 24 hours or stayed more than 3 days in ICU ; On-pump heart surgery; more than 6 units Blood transfusion; duration of surgery > 6 hours or duration of Pump time more >120 minutes or aorta clamping time > 60 minutes; insertion of intra aortic balloon pump; use high dose of inotropes; Emergent surgery; The presence of Comorbidities (e.g. liver failure , renal failure (serum creatinine > 2).

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **370**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization performed by Random Number Generator software

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Science

Street address

Babol Ayatollah Rouhani Hospital, Ganjafrooz Street

City

Babol

Postal code

Approval date

2017-07-16, 1396/04/25

Ethics committee reference number

MUBABOL.HRI.REC.1396.10

Health conditions studied

1

Description of health condition studied

Surgical Site Infection

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Infection rate

Timepoint

48h after the surgery, 7-10 days after the surgery, 30 days after the surgery

Method of measurement

Wound observation

Secondary outcomes

1

Description

Responsible pathogens for infection

Timepoint

-

Method of measurement

Wound secretion culture

2

Description

Drug resistance

Timepoint

-

Method of measurement

Antibiogram

Intervention groups

1

Description

Intervention group 1: Received amp cefazolin 1 gr Iv q 6 hours for 48 h and then cap cephalixin 500 mg q 6 hours for 5 days (Farabi pharmaceutical company).

Category

Treatment - Drugs

2

Description

Intervention group 2: Received amp cefazolin 1 gr Iv q 6 hours for 48 h and then placebo q 6 hours for 5 days (Farabi pharmaceutical company).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Ayatollah Rouhani Hospital

Full name of responsible person

Mostafa Javanian

Street address

Babol Ayatollah Rouhani Hospital, Ganjafrooz Street

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor Of Research Babol University Of Medical Sciences

Full name of responsible person

Mostafa Javanian

Street address

Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor Of Research Babol University Of Medical Sciences

Proportion provided by this source

100

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

Babol University Of Medical Sciences

Full name of responsible person

Mostafa Javanian

Position

Associate professor of infectious and tropical diseases

Other areas of specialty/work

Street address

Infectious and tropical diseases Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code

Phone

+98 11 3223 8301

Fax

Email

m.javanian@mubabol.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babaol University Of Medical Sciences

Full name of responsible person

Mosatafa Javanian

Position

associate professor of infectious and tropical diseases

Other areas of specialty/work

Street address

infectious and tropical diseases Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code

Phone

+98 11 3223 8301

Fax

Email

m.javanian@mubabol.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Babaol University Of Medical Sciences

Full name of responsible person

Zahra Aliramaji

Position

Resident in training of infectious and tropical diseases

Other areas of specialty/work

Street address

infectious and tropical diseases Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code

Phone

+98 11 3223 8301

Fax

Email

zahraaliramaji@yahoo.com

Web page address

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