

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of two prophylactic antibiotic regimens (cefazolin and cefazolin+gentamicin) on surgical wound infection of CABG patients

Protocol summary

Summary

The aim of this randomized clinical trial is to Comparison of two prophylactic antibiotic regimens (cefazolin and cefazolin+gentamicin) on surgical wound infection of CABG patients in Mazandaran Heart Center. Inclusion criteria are informed written consent; Age between 40 and 75 years; Elective CABG surgery; Use of the cardiopulmonary pump during surgery. Exclusion criteria are history of infectious disease and use of antibiotic during previous week; Renal failure (baseline serum creatinine > 2mg/dl); systemic disease and drugs causing immunosuppression; together with other cardiac surgery (valvular surgery); Reoperation; Ejection fraction < 35%; history of sensitivity to cephalosporin or Gentamicin. A total of 400 patients, meeting eligibility criteria, are randomly allocated into two equal groups. In the first group the prophylactic regimen consists of Cefazolin 2 g IV before sternal incision followed by 1 g IV every 6 hours for 72 hours. In the second group the prophylactic regimen consists of Cefazolin 2 g IV plus Gentamicin 1.5mg/kg IV before sternal incision followed by Cefazolin 1 g IV every 6 hours plus Gentamicin 1.5mg/kg IV every 8 hours for 72 hours. Patients are observed by cardiac surgeon for signs of surgical wound infection at 3, 7, 21 and 30 days after cardiac surgery and results are recorded in the data collection form.

General information

Acronym

CABG: Coronary Artery Bypass Graft

IRCT registration information

IRCT registration number: **IRCT201201114365N10**

Registration date: **2012-02-01, 1390/11/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-02-01, 1390/11/12

Registrant information

Name

Afshin Gholipour Baradari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2011-02-20, 1389/12/01

Expected recruitment end date

2011-11-21, 1390/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two prophylactic antibiotic regimens (cefazolin and cefazolin+gentamicin) on surgical wound infection of CABG patients

Public title

Comparison of two prophylactic antibiotic regimens (cefazolin and cefazolin+gentamicin) on surgical wound infection of CABG patients

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria are informed written consent; Age between 40 and 75 years; Elective CABG surgery; Use of the cardiopulmonary pump during surgery. Exclusion criteria are history of infectious disease and use of antibiotic during previous week; Renal failure (baseline serum creatinine > 2mg/dl); systemic disease and drugs causing immunosuppression; together with other cardiac surgery (valvular surgery); Reoperation; Ejection fraction < 35%; history of sensitivity to cephalosporin or Gentamicin.

Age
From **40 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **400**

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 Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Moallem Square

City

Sari

Postal code

46175866

Approval date

2011-02-16, 1389/11/27

Ethics committee reference number

90-137

Health conditions studied

1

Description of health condition studied

Prophylactic antibiotic

ICD-10 code

Z29.2

ICD-10 code description

Prophylactic antibiotic therapy

Primary outcomes

1

Description

surgical wound infection

Timepoint

3, 7, 21 and 30 days after cardiac surgery

Method of measurement

observation - culture

Secondary outcomes

1

Description

Creatinine

Timepoint

2 -4 days after surgery

Method of measurement

Laboratory kit - mg/dl

Intervention groups

1

Description

In the first group the prophylactic regimen consists of Cefazolin 2 g IV before sternal incision followed by 1 g IV every 6 hours for 72 hours.

Category

Treatment - Drugs

2

Description

In the second group the prophylactic regimen consists of Cefazolin 2 g IV plus Gentamicin 1.5mg/kg IV before sternal incision followed by Cefazolin 1 g IV every 6 hours plus Gentamicin 1.5mg/kg IV every 8 hours for 72 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran Heart center

Full name of responsible person

Afshin Gholipour Baradari

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati MD

Street address

Mazandaran university of medical sciences, Moallem Square

City

Sari

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 of Mazandaran 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**

Mazandaran University Of Medical Sciences

Full name of responsible person

Afshin Gholipour Baradari MD

Position

CCMF, Assistant Professor, Chief of ICU

Other areas of specialty/work**Street address**

Mazandaran University of Medical Sciences, Moallem Square

City

Sari

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

Mazandaran University Of Medical Sciences

Full name of responsible person

Rahman Ghafari MD

Position

Assistant Professor, Cardiac Surgeon

Other areas of specialty/work**Street address**

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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