# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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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+98 11 3326 1245

**Email address**

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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

**Street address**
Mazandaran Heart center, Artesh Blvd
**City**
Sari

## 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**
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## Person responsible for scientific inquiries

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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*