Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Prophylactic effect of cefazolin-vancomycin versus ceftazidime-vancomycin on the infection of surgical site in patients undergoing open heart surgery: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the prophylactic effect of cefazolin-vancomycin versus ceftazidime-vancomycin on the infection of the surgical site in patients undergoing open-heart surgery

Design
This is a double-blind randomized clinical trial, phase II, in which 434 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible patients undergoing open-heart surgery will refer to Farshchian Heart Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 65 years, Indication of open-heart surgery. Hospitalization for more than three days Exclusion criteria: Hemodialysis patients, History of recurrent Freonocellus, Having an artificial valve or vascular graft

Intervention groups
Intervention group 1: Cefazoline injection 2 to 3 g depending on patient's weight every 6 hours and vancomycin injection 15 mg/kg every 12 hours for 48 hours Intervention group 2: Ceftazidime injection 1 g every 8 hours and vancomycin injection 15 mg/kg every 12 hours for 48 hours

Main outcome variables
Primary outcome: Superficial infection at the surgical site

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N324**
Registration date: **2019-12-17, 1398/09/26**
Registration timing: **prospective**

Last update: **2019-12-17, 1398/09/26**
Update count: **0**

Registration date
2019-12-17, 1398/09/26

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-05, 1398/10/15

Expected recruitment end date
2022-01-05, 1400/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Prophylactic effect of cefazolin-vancomycin versus ceftazidime-vancomycin on the infection of surgical site in patients undergoing open heart surgery: a double-blind randomized clinical trial

Public title
Prophylactic effect of cefazolin-vancomycin versus ceftazidime-vancomycin on the infection of surgical site in patients undergoing open heart surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 18 to 65 years, Indication of open heart surgery. Hospitalization for more than three days

Exclusion criteria:
Hemodialysis patients, History of recurrent Freonocellus, Having an artificial valve or vascular graft

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **434**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The shape of the medications will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2019-11-23, 1398/09/02

Ethics committee reference number
IR.UMSHA.REC.1398.689

Health conditions studied

1

Description of health condition studied
Surgical wound infection

ICD-10 code
O86.0

ICD-10 code description
Infection of obstetric surgical wound

Primary outcomes

1

Description
Superficial infection at the surgical site

Timepoint
On days 7, 14, 30 and 90 after surgery

Method of measurement
With clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Cefazoline injection 2 to 3 g depending on patient's weight every 6 hours and vancomycin injection 15 mg/kg every 12 hours for 48 hours

Category
Treatment - Drugs

2

Description
Intervention group 2: Ceftazidime injection 1 g every 8 hours and vancomycin injection 15 mg/kg every 12 hours for 48 hours

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Farshchian Heart Hospital in Hamadan city

Full name of responsible person
Dr Soroor Akbari

Street address
Farshchian Heart Hospital, Shahid Fahmideh Ave.

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Hamadan

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6517838695

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Saeid Bashirian

Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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
Hamedan University of Medical Sciences

Proportion provided by this source
100

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr Soroor Akbari

Position
Infectious Disease Specialist

Latest degree
Medical doctor

Other areas of specialty/work
Infectious diseases

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School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

Contact

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Full name of responsible person
Dr. Jalal Poorolajal

Position
Professor of Epidemiology

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available