

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 1740

Email

suak1393@gmail.com

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

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

Street address

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

suak1393@gmail.com

Person responsible for scientific 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

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Other areas of specialty/work

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Phone

+98 81 3838 0572

Email

suak1393@gmail.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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