Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of intraarticular vancomycin in preventing infection in patients undergoing hip hemiarthroplasty

Protocol summary

Study aim
Investigating the effects of intraarticular vancomycin in preventing infection in patients undergoing hip hemiarthroplasty

Design
The clinical trial has two groups including control and intervention in parallel groups. Randomization will be done in permutation blocks of four, which will be done on 48 patients.

Settings and conduct
The place of study is Golestan and Imam Khomeini hospitals in Ahvaz. Surgeries will be performed in the general operating room of these two hospitals under the supervision of professors in a fixed setting, and the follow-up of patients after the operation will be done in the orthopedic clinic of these two hospitals.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Age over 50 years - Femoral neck fracture patients candidates for primary hip hemiarthroplasty - Patient consent to participate in the study Exclusion criteria: - Presence of active, local or systemic infections - Patients with a history of infection in the hip joint on the same side - Patients with skin disorders in surgery site - Patients undergoing revision surgery - Patients with known allergy to vancomycin - Renal disease and patients with high creatinine before surgery - Auditory problems

Intervention groups
The intervention group receive intrawound vancomycin after hip hemiarthroplasty The control group does not receive intraoperative vancomycin.

Main outcome variables
Superficial infection and deep infection of the surgery site

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230703058652N1**
Registration date: **2023-09-13, 1402/06/22**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-13, 1402/06/22**
Update count: **0**

Registration date
2023-09-13, 1402/06/22

Registrant information

Name
Mohsen Asgari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 84 3363 8301

Email address
mohsenasgari8@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-21, 1402/03/31

Expected recruitment end date
2023-10-22, 1402/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of intraarticular vancomycin in preventing infection in patients undergoing hip hemiarthroplasty

Public title

intraarticular vancomycin in hip hemiarthroplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Femoral neck fracture patients candidates for primary hip hemiarthroplasty Age over 50 years Patient consent to participate in the study

Exclusion criteria:

patients that are candidate for total hip arthroplasty known allergy to vancomycin patients with renal disease and those have high creatinin level active infection, local or systemic patients with skin disorders in surgery site patients undergo revision surgery Auditory disorders immunocompromization

Age

From **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

from 48 patients that will meet the conditions for entering the study, they will be randomized using the block randomization method and blocks size of four and will be divided into two groups receiving vancomycin and the group not receiving vancomycin in surgery wound. According to the number of study patients, which is 48, the number of 12 blocks with size of 4 is determined for each block. After determining the number of blocks and the capacity of each block, randomization of patients within the block is done using pre-written cards. We consider group A as the group receiving vancomycin in the surgery wound, and group B as the group that does not receive vancomycin powder in the surgery wound. 2 cards named A and 2 cards named B are prepared , and we write the numbers 1 to 4 on the back of the cards, the number 1 is on the back of the A card, the number 2 is on the back of the B card, the number 3 is on the next A card, and the number 4 is on the next B card. Then, by using the engineering calculator and choosing the RAND option and choosing the interval 1-4, we get random numbers from 1-4 and according to the number obtained from the calculator, we take the card and look at the back of it to see that A or It is B and the first card is placed in the first house of the first block, the second card is placed in the second house of the first block, the third card is placed in the third house of the first block, and the fourth card is placed in the fourth house of the first block. We do this for all 12 blocks. And during the surgery of the patients, we start from the first house of the first block. If it is group A, vancomycin powder will be poured into the wound, and if it is group B, vancomycin powder will not be poured into the wound. And for the next patients, we will select their groups from the first to the twelfth block respectively.

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 Ahwaz jondishapour University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Esfand Ave, Golestan Blvd., Ahvaz, Iran.

City

Ahvaz

Province

Khouzestan

Postal code

6136683813

Approval date

2023-06-17, 1402/03/27

Ethics committee reference number

IR.AJUMS.REC.1402.160

Health conditions studied

1

Description of health condition studied

Femoral neck fracture

ICD-10 code

S72.0

ICD-10 code description

Fracture of head and neck of femur

Primary outcomes

1

Description

Deep infection of surgery site

Timepoint

7 , 14 , 30 , 60 , 90 days after surgery

Method of measurement

Inspection and physical examination

2

Description

Superficial infection of surgery site

Timepoint

7 , 14 , 30 , 60 , 90 days after surgery
Method of measurement
Inspection and physical examination

Secondary outcomes

1

Description
Erythrocytecsedimentation rate
Timepoint
Before surgery and one month after surgery
Method of measurement
By blood test

2

Description
C- reactive protein
Timepoint
Before surgery and one month after surgery
Method of measurement
By blood test

Intervention groups

1

Description
Intervention group: a group of patients who, after surgery, one gram of vancomycin powder will be poured into their surgical wound, and after that, the subcutaneous fascia and skin will be repaired.
Category
Prevention

2

Description
Control group: a group of patients who will not receive vancomycin powder in the surgical site after surgery, but all surgical procedures are similar except for receiving vancomycin powder.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital
Full name of responsible person
Mohsen asgari
Street address
Azadegan Street, Imam Khomeini Hospital, Ahvaz, Iran.
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6193673166
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2

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
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Postal code
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Email
GOLESTANHOSPITAL@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoosh zakerkish
Street address
Jundishapur University of Medical Sciences, Esfand Ave, Golestan Blvd., Ahvaz, Iran
City
Ahvaz
Province
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Postal code
6135715749
Phone
+98 61 3311 3861
Email
mohsenasgari8@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mohsen asgari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Azadegan Street, Imam Khomeini Hospital, Ahvaz, Iran.

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Phone

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Payam mohammadhosseini

Position

Associate proffesor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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City

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Phone

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Email

mohsenasgari8@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The data file will be shared in the format of spss software. It should be noted that only the information related to the main consequences will be possible to share.

When the data will become available and for how long

Data access will start 6 months after publication

To whom data/document is available

The data will be available to researchers working in academic institutions.

Under which criteria data/document could be used

Data will only be available for use in review studies and meta-analyses.

From where data/document is obtainable

Payam mohammadhosseini by academic email mohammadhoseini-p@ajums.ac.ir

What processes are involved for a request to access

data/document

First, send an email to the author and mention the purpose of receiving the information. If there is no problem, you will receive the information one to three weeks later.

Comments