Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of local vancomycin powder in the prevention of surgical site infections in posterior spinal surgeries

Protocol summary

Study aim

The site of infection is one of the most commonly reported postoperative cases. The purpose of this study was to evaluate the effect of topical vancomycin powder on the prevention of local infection site infection in spinal surgery.

Design

This is a blind double blind clinical trial performed in Imam Khomeini hospital in Sari. Considering the 95% confidence level and 90% probability of testing, 100 patients were assigned to each group. Eligible patients are assigned to two groups using random numbers and based on their sample size

Settings and conduct

This is a double blind clinical trial that will be conducted to evaluate the effect of topical venecomycin powder on the prevention of site infections in posterior posterior spinal surgery in Imam Khomeini Hospital, Sari.After selecting the samples, the patients were randomly assigned to the two groups by randomization. One group received vancomycin and the control group who received only prophylaxis (intravenous only intravenous cesophageal) and another evaluated the surgical site.

Participants/Inclusion and exclusion criteria

Inclusion :Patients admitted to the neurological surgery department due to lumbar spinal cord stenosis, vertebral instability, DJD changes, and spinal trauma are candidates for surgical decompression of the spinal cord channel or spinal fusion. Exit : Dora rupture during surgery - Revision action- Age under 18 and over 85 years - Chronic renal failure- Use of cortico steroids and immuno suppressive drugs --Diabetes mellitus

Intervention groups

Prevention and control of infection site by using vancomycin powder in the surgical site.

Main outcome variables

Infection of the site of surgery, including the secretion of the ulcer and the secretion of the site of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180826040869N1**
Registration date: **2018-09-25, 1397/07/03**
Registration timing: **retrospective**

Last update: **2018-09-25, 1397/07/03**
Update count: **0**

Registration date

2018-09-25, 1397/07/03

Registrant information

Name

Misagh Shafizad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1700

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-08, 1395/03/19

Expected recruitment end date

2017-06-09, 1396/03/19

Actual recruitment start date

2016-06-13, 1395/03/24

Actual recruitment end date

2017-07-08, 1396/04/17

Trial completion date

2017-07-08, 1396/04/17

Scientific title

The effectiveness of local vancomycin powder in the prevention of surgical site infections in posterior spinal surgeries

Public title

The effectiveness of local vancomycin powder in the prevention of surgical site infections in posterior spinal surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Spinal cord stenosis Vertical instability DJD changes Spinal trauma Age between 18 and 85 years

Exclusion criteria:

Dora tear during surgery Revision operation Age under 18 and over 85 years Chronic renal failure Taking corticosteroids and immunosuppressive drugs Diabetes mellitus

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **200**

Actual sample size reached: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

The referral who will be admitted to the study will be selected based on Comorbid conditions, including the presence or absence of diabetes, and the timing of the matching procedure. Each person is given a code and using the table. Random numbers are divided into two groups of 100 on the conditions of comorbid conditions including the presence or absence of diabetes and the time of matching surgery) Takes place

Blinding (investigator's opinion)

Double blinded

Blinding description

After selecting the samples, the patients were randomly assigned to the two groups by randomization. One group received vancomycin and the control group who received only prophylaxis (intravenous only intravenous cesophageal) and another evaluated the surgical site.

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

Amir mazandrani Blvd sari Town

City

Sari

Province

Mazandaran

Postal code

4816633131

Approval date

2016-10-06, 1395/07/15

Ethics committee reference number

IR.MAZUMS.REC.1395.2175

Health conditions studied

1

Description of health condition studied

Lumbar spinal cord stenosis- vertebral instability- DJD changes- -spinal trauma candidates candidate- surgery for decompression of the spinal cord - spinal fusion

ICD-10 code

M99.3

ICD-10 code description

Osseous stenosis of neural canal

Primary outcomes

1

Description

Percentage of people who have a surgical wound infection

Timepoint

Patients will be screened for infection two weeks, one month and two months after surgery.

Method of measurement

An infection site of the surgery, including the secretion and opening of the wound, from the cultures of the site of the operation to confirm the presence of the infection will be used. The ESR test also has a positive CRP.wound, will be used to determine the presence of the infection.

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, on the day of preoperative surgery, one gram of intravenous cefazolin is used at the

end of the surgery before closing the wound with 1 g of vancomycin powder locally in the wounds below 10 cm and 5.1 g for wounds greater than 10 cm. All Patients will be screened again for two weeks, one month and two months after the operation, and the condition of the wound will be investigated for infection. In cases of suspected surgery site infection, including the secretion and opening of the wound, the cultures of the site will be used to confirm the presence of the infection. ESR and CRP are also checked.

Category

Treatment - Drugs

2

Description

Control group: In the control group, only the patient will receive an antibiotic prophylaxis (1 g of venous cefazolin) before surgery, and as an interventional surgical wound for two weeks, one and two months later, the infection will be monitored.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Hospital
Full name of responsible person
Misagh Shafizad
Street address
Amir Mazandarani Blvd ,Sari Town
City
Sari
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeidi
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Moalem Blvd., Sari Town
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۴۸۱۵۷-۳۳۹۷۱
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Fax
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Email
saedi@domian.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sari 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
Mazandaran University of Medical Sciences
Full name of responsible person
Misagh Shafizad
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Misagh Shafizad
Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Misagh Shafizad

Position

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Latest degree

Specialist

Other areas of specialty/work

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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

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

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

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

--

What processes are involved for a request to access data/document

-

Comments