Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Local Vancomycin Therapy to Reduce Surgical Site Infection in Spine Surgery: A Randomized Prospective Study

Protocol summary

Study aim
The effect of applying local vancomycin in reducing the rate of postoperative infection in spinal surgeries

Design
Clinical trial with control group, with parallel groups, one-way blind, randomized, phase 3 on 360 patients. The web was used for randomization.

Settings and conduct
In the control group, sutures were routinely applied in 3 layers of fascia, subcutaneous and cutaneous skin. After washing the wound site in the treatment group, in cases up to 2 levels of spine surgery, 1 gram, and in cases more than 2 levels, 2 grams of vancomycin were used. The antibiotic powder was poured on muscles, bones, and subcutaneous tissue, but not on the dura and fusion site.

Participants/Inclusion and exclusion criteria
Inclusion criteria included all patients over 18 years of age who underwent open spinal surgery in the cervical, thoracic and lumbosacral regions Exclusion criteria included the following: 1.Previous history of spine infection 2. History of immunodeficiency or ongoing chemotherapy 3. History of kidney or liver failure 4. Allergy to vancomycin or cephalosporin 5. Inability to follow up to 3 months after surgery 6.primary or metastatic spinal cord or spine tumors 7. Dissatisfaction with the study.

Intervention groups
Application of topical vancomycin powder at the site of surgical incision on fascia, muscles and subcutaneous tissue after surgery and before closing the surgical site in the intervention group,No drug or placebo is used in the control group

Main outcome variables
Surgical site infections

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210712051848N1**
Registration date: **2021-08-13, 1400/05/22**
Registration timing: **retrospective**

Last update: **2021-08-13, 1400/05/22**
Update count: **0**

Registration date
2021-08-13, 1400/05/22

Registrant information

Name
Hamid Reza Khayat Kashani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7343 0000

Email address
khayatkashani@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-01, 1398/06/10

Expected recruitment end date
2020-09-10, 1399/06/20

Actual recruitment start date
2019-09-09, 1398/06/18

Actual recruitment end date
2020-08-01, 1399/05/11

Trial completion date
2020-11-20, 1399/08/30

Scientific title
Local Vancomycin Therapy to Reduce Surgical Site Infection in Spine Surgery: A Randomized Prospective Study

Public title
The efficacy of local vancomycin on postoperative infection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients over 18 years of age who underwent open spinal surgery in the cervical, thoracic and lumbosacral regions
Exclusion criteria:
Previous history of spine infection History of immunodeficiency or ongoing chemotherapy History of kidney or liver failure Allergy to vancomycin or cephalosporin Inability to follow up to 3 months after surgery Primary or metastatic spinal cord or spine tumors Dissatisfaction with the study.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **360**
Actual sample size reached: **370**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, the web-based randomization method is used. The individual randomization unit is a sealed envelope randomization tool, and the samples are randomly divided into 2 groups with equal numbers. www.Randomization.com is used to random allocation. The method of Sequentially numbered, sealed, opaque envelopes is used for allocation concealment
Blinding (investigator's opinion)
Single blinded
Blinding description
The patient participating in the study is not aware of her/his group and due to the fact that vancomycin powder is used under anesthesia, there is no need to use a placebo.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Medical School, Shahid Beheshti University of Medical Sciences
Street address
School of Medicine, Shahid Beheshti University of Medical Sciences, Koodkiar St., Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2019-08-27, 1398/06/05
Ethics committee reference number
IR.SBMU.MSP.REC.1398.494

Health conditions studied

1

Description of health condition studied
Surgical site infections
ICD-10 code
T84.6
ICD-10 code description
Infection and inflammatory reaction due to internal fixation device [any site]

Primary outcomes

1

Description
Discharge from the wound
Timepoint
The wound site is examined at the time of discharge, two weeks after surgery, and 3 months after surgery
Method of measurement
Physical examination and history

2

Description
Swelling of the operation site
Timepoint
The wound site is examined at the time of discharge, two weeks after surgery, and 3 months after surgery
Method of measurement
Physical examination and history

3

Description
Redness of the operation site
Timepoint
The wound site is examined at the time of discharge, two weeks after surgery, and 3 months after surgery
Method of measurement
Physical examination and history

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: after surgery and irrigation with normal saline, vancomycin powder is used locally in the intervention group. If the level to be operated is one level, one gram is used and if it is more than one level, two grams of vancomycin are used. The vancomycin used is made by Exir Pharmaceutical Company and it is used on muscles, subcutaneous tissue and fascia. The skin and fascia are then repaired.

Category
Treatment - Drugs

2

Description
Local drug or placebo is not used. After surgery, the operation site is irrigated with normal saline and the fascia, muscles and skin are closed in several layers.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hosein Hospital

Full name of responsible person
Hamid Reza Khayat Kashani

Street address
Madani Street

City
Tehran

Province
Tehran

Postal code
1617763141

Phone
+98 21 7343 0000

Fax
+98 21 7755 7069

Email
hrkhka@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zargi

Street address
Shahid Beheshti University of Medical Sciences, Shahid Arabi St., Next to Ayatollah Taleghani Hospital, Yemen St., Shahid Chamran Highway

City
Tehran

Province
Tehran

Postal code
1983969411

Phone
+98 21 2990 2233

Email
info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hamid Reza Khayat Kashani

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

Street address
Imam Hossein Hospital, Shahid Madani St., Imam Hossein Square

City
Tehran

Province
Tehran

Postal code
1617763141

Phone
+98 21 7343 0000

Email
hrkhka@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hamid Reza Khayat Kashani

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

Street address
Imam Hossein Hospital, Shahid Madani St., Imam Hossein Square

City
Tehran

Province
Tehran

Postal code
1617763141

Phone
+98 21 7343 0000

Email
hrkhka@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hamid Reza Khayat Kashani

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

Street address
Imam Hossein Hospital, Shahid Madani St., Imam Hossein Square

City
Tehran

Province
Tehran

Postal code
1617763141

Phone
+98 21 7343 0000

Email
hrkhka@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
The study data is shared at the request of researchers after deleting personal details and identifying individuals

When the data will become available and for how long
Access to data starts from the time the results are published.

To whom data/document is available
Data will be sent to all researchers who request it

Under which criteria data/document could be used
The use of the requested data for meta-analysis is permitted in systematic review studies

From where data/document is obtainable
Researchers can contact Dr. Hamid Reza Khayat Kashani for the data in the following ways:Email: hrkhka@gmail.com Tel: 00989131625625 Address: Neurosurgery Department,Imam Hosein Hospital, Madani Street, Tehran, Iran

What processes are involved for a request to access data/document
After the researcher's request to receive the data, it is referred to the research deputy of the neurosurgery department, and after reviewing the researcher's profile and his request on how to use the data, if agreed, the data will be sent to him or her. Otherwise, he/she will be informed of the reason for not sending the data, and this process will take less than a month.

Comments