

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effects of preoperative use of povidone iodine-impregnated dressing on postoperative rate of surgical site infection in patients undergoing posterior lumbar spinal fusion surgery

Protocol summary

Study aim

This study aims to evaluate the effects of preoperative use of povidone iodine-impregnated dressing on postoperative rate of surgical site infection in patients undergoing posterior lumbar spinal fusion surgery.

Design

This study is a two-arm, parallel-group, open-label, randomized controlled trial, including 160 patients undergoing posterior spinal fusion surgery.

Settings and conduct

Given the nature of the study intervention, no blinding will be performed. This study will be performed in neurosurgery department of Shohada Tajrish hospital.

Participants/Inclusion and exclusion criteria

Patients undergoing posterior spinal fusion surgery will be included in this clinical trial. Patients with prior history of hypersensitivity reaction to study drug, active or history of spinal infection, and intradural spinal pathology will be excluded from the study.

Intervention groups

Patients will be randomly divided into two groups, including intervention and control. Patients in the intervention group will receive a sterile gauze soaked in 10% povidone iodine solution 12 hours before the operation, which will be placed over the anticipated incision site. Patients in the control group will receive no placebo and undergo standard perioperative care.

Main outcome variables

The primary outcome measure of the study will be the incidence of surgical site infection during the postoperative 30 days.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200502047277N10**

Registration date: **2022-10-03, 1401/07/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-03, 1401/07/11**

Update count: **0**

Registration date

2022-10-03, 1401/07/11

Registrant information

Name

saeed oraee yazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 25719

Email address

saeed_o_yazdani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of preoperative use of povidone iodine-impregnated dressing on postoperative rate of surgical site infection in patients undergoing posterior lumbar

spinal fusion surgery

Public title
Povidone iodine-impregnated dressing and surgical site infection in spine surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing posterior lumbar spinal fusion surgery
Written informed consent
Exclusion criteria:
Prior hypersensitivity reaction to study drug
Active or history of spinal infection
Intradural spinal pathology

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization (1:1) with a block size of 4 will be performed using the SPSS 24, and sealed opaque envelopes will be used for allocation concealment. In SPSS, after dividing the study population into blocks, random numbers between 0 and 1 will be generated for each patient using RV.UNIFORM(0,1) and after determining the rank within each block, the two lower ranks will be assigned to treatment group 1, and the two upper ranks will be assigned to treatment group 2. Except for the surgeon performing the study intervention, patients, principal investigator, outcome assessors, and data analyzers will remain blind to the randomization and allocation.

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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences
,Shahid Arabi St., Yemen St., Shahid Chamran Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-04-24, 1401/02/04

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.043

Health conditions studied

1

Description of health condition studied

Infection following a procedure

ICD-10 code

T81.4

ICD-10 code description

Infection following a procedure

2

Description of health condition studied

Fusion of spine

ICD-10 code

M43.2

ICD-10 code description

Fusion of spine

Primary outcomes

1

Description

Incidence of surgical site infection

Timepoint

During the first postoperative 30 days, including daily during the hospitalization and weekly after discharge

Method of measurement

Physical examination (during the hospitalization) and telephone call (after discharge)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the study intervention group will receive a sterile gauze soaked in povidone iodine 10% solution, which will be placed over the anticipated incision site 12 hours before the operation.

Category

Prevention

2

Description

Control group: Patients in the control group will receive the standard preoperative care with no placebo.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Saeed Oraee Yazdani

Street address

Shohadaye Tajrish Hospital, Tajrish Square, Tehran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Afshin Zarghi

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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

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

Saeed Oraee Yazdani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Latest degree

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Person responsible for updating data

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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