Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the effects of local intraoperative epidural use of triamcinolone-soaked Gelfoam with normal saline -soaked Gelfoam on postoperative outcomes in patients undergoing posterolateral lumbar spinal fusion surgery

Protocol summary

Study aim

This study aims to compare the effects of intraoperative local epidural administration of triamcinolone acetonide-soaked Gelfoam on postoperative outcomes of patients undergoing posterolateral spinal fusion surgery, with normal saline-soaked Gelfoam.

Design

This study is a single center, phase 3, parallel group, double-blind, randomized, palacebo-controlled trial with 100 patients.

Settings and conduct

This study will be performed in the neurosurgery department of Shohada e Tajrish hospital. In the present study, 100 patients undergoing posterolateral lumbar spinal fusion will be randomly assigned into two groups (1:1) including treatment and control groups. Patients, outcome assessors, and data analyzers will be blind throughout the study. The surgeon who performs the operations will not be blind to the intervention and patient allocation.

Participants/Inclusion and exclusion criteria

Patients who undergo posterolateral lumbar instrumented spinal fusion surgery for degenerative indications will be included in the present study. Patients with non-degenerative indications such as tumor, trauma, and infection, as well as ASA physical status> 2 will be excluded.

Intervention groups

Patients in the intervention group will receive a Gelfoam soaked in 1 ml of triamcinolone acetonide (40 mg). The Gelfoam will be placed over the nerve roots intraoperatively. Patients in the control group will receive a Gelfoam soaked in 1 ml of normal saline similarly.

Main outcome variables

The primary outcome measure of the study is postoperative pain according to the 10-point visual analog scale (VAS) at rest and with movement. Secondary outcome measures are cumulative postoperative 24 h morphine consumption, Oswestry Disability Index (ODI), length of stay, postoperative nausea and vomiting (PONV), and the incidence of postoperative complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200502047277N6**
Registration date: **2021-09-29, 1400/07/07**
Registration timing: **prospective**

Last update: **2021-09-29, 1400/07/07**
Update count: **0**

Registration date

2021-09-29, 1400/07/07

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

2021-10-01, 1400/07/09

Expected recruitment end date

2022-01-01, 1400/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of local intraoperative epidural use of triamcinolone-soaked Gelfoam with normal saline - soaked Gelfoam on postoperative outcomes in patients undergoing posterolateral lumbar spinal fusion surgery

Public title

Steroids in posterior spinal fusion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age greater than 18 years Degenerative indications for elective posterior instrumented lumbar spinal fusion surgery Written informed consent

Exclusion criteria:

Non-degenerative pathologies (e.g., tumor, trauma, deformity, or infection) Hypersensitivity reaction to the study drug American Society of Anesthesiologists (ASA) physical status> 2 Concurrent psychiatric disorder

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

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)

Double blinded

Blinding description

Patients, the principal investigator, outcome assessors, and data analyzers will be blind to the study intervention. For allocation concealment, sealed opaque envelopes will be used (treatment 1 or 2). Due mainly to the nature of the study intervention, the surgeon will not be blind to the allocation process and intervention received by the patients and will perform the study intervention or placebo based on the study group (treatment 1 or 2). The surgeon will remain out of the process of data collection, outcome assessment, or analysis. Postoperatively, all patients, outcome assessors and analyzers, and the principal investigator will only know the study group (treatment 1 or 2) and will remain blind to the intervention performed in each group throughout the study.

Placebo

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

2020-11-22, 1399/09/02

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.710

Health conditions studied

1

Description of health condition studied

Fusion of spine, lumbar region

ICD-10 code

M43.26

ICD-10 code description

Fusion of spine, lumbar region

Primary outcomes

1

Description
10-point visual analog scale (VAS) for postoperative pain
Timepoint
baseline, 2, 4, 6, 12, 24, and 48 h with 1, 4, and 12 weeks postoperatively
Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Cumulative postoperative 24 h morphine consumption
Timepoint
24 h postoperatively
Method of measurement
Patient-controlled analgesia device

2

Description
Oswestry disability index (ODI)
Timepoint
1 and 4 weeks postoperatively
Method of measurement
Questionnaire

3

Description
Length of stay
Timepoint
Until discharge
Method of measurement
follow-up

4

Description
Postoperative nausea and vomiting
Timepoint
Every 4 h for 24 h postoperatively
Method of measurement
follow-up and observation

5

Description
Postoperative complications
Timepoint
Once a week for 12 weeks after the surgery
Method of measurement
follow-up and observation

Intervention groups

1

Description
Intervention group: A Gelfoam soaked in 1 ml of triamcinolone acetonide (40 mg/ml, TriamHEXAL; HEXAL AG, Holzkirchen, Germany) for five minutes, will be placed placed over the nerve roots. After the placement of Gelfoam, the surgical closure will be performed.
Category
Treatment - Drugs

2

Description
Control group: Similar to the treatment group, a Gelfoam soaked in 1 ml of normal saline for five minutes, will be placed over the nerve roots. After the placement of Gelfoam, the surgical closure will be performed.
Category
Placebo

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.
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
Saeed_o_yazdani@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
19839-63113
Phone

+98 21 2243 9770

Email

Intl_office@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

Roozbeh Tavanaei

Position

Research associate

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Functional Neurosurgery Research Center (FNRC), SBMU Shohada-E-Tajrish Educational Hospital, Tajrish Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2270 1022

Email

rtavanaei@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeed Oraee yazdani

Position

Neurosurgeon

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Tajrish

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Fax

Email

saeed_o_yazdani@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Pooria Ahmadi

Position

Research associate

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Functional Neurosurgery Research Center (FNRC), SBMU Shohada-E-Tajrish Educational Hospital, Tajrish Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2270 1022

Email

p.ahmadi.13@gmail.com

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