

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 acetamide-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, placebo-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 acetamide (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 oraei 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**

Roosbeh 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 yezdani

**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