

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Investigating the Effect of Erector Spinae Plane Block during Posterior Cervical Spine Fusion Surgery with Lateral Mass Fixation on Postoperative Axial Pain

Protocol summary

Study aim

Investigating the effect of erector spinae plane block during posterior cervical spine fusion surgery with lateral mass fixation on postoperative occipital pain.

Design

clinical trial included a control group and parallel, double-blind, randomized, phase 2 groups, conducted on 60 patients. Block randomization method was used for randomization.

Settings and conduct

The study is designed to be conducted on two groups of patients undergoing posterior cervical spine fusion surgery with lateral mass fixation. A total of 60 patients will be assigned to the intervention and control groups using block randomization. One group of 30 patients will receive injections of bupivacaine and dexamethasone into the erector spinae muscles, while the other group of 30 patients will receive a placebo. The study will be double-blind, meaning that the patient, investigator, drug injector, and statistical analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Absence of lower limb paralysis before surgery, age between 18 and 65 years, fusion in the range of C3 to C7. Exclusion criteria: Pregnancy, decreased lower limb force after surgery, acute neck trauma, site infection, simultaneous anterior cervical surgery, patient's reason for surgery is tumor addiction to drugs (excluding smoking).

Intervention groups

In the intervention group, a combination of bupivacaine and dexamethasone is injected throughout the muscles at the site of skin incision, but in the control group, a placebo is injected.

Main outcome variables

NRS scores at 6 hours, 24 hours, 48 hours, and 1 week after surgery; the first time the patient requested analgesics; the amount and type of analgesic used; the

time to first ambulation after surgery; age; gender; number of cervical fusion levels; smoking status; presence of myelopathy changes in MRI; presence of radicular pain; and type of underlying pathology

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230504058083N1**

Registration date: **2023-10-15, 1402/07/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-15, 1402/07/23**

Update count: **0**

Registration date

2023-10-15, 1402/07/23

Registrant information

Name

Mohammad Rostami ravari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2026-03-20, 1404/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Effect of Erector Spinae Plane Block during Posterior Cervical Spine Fusion Surgery with Lateral Mass Fixation on Postoperative Axial Pain

Public title
Investigating the Effect of Erector Spinae Plane Block during Posterior Cervical Spine Fusion Surgery with Lateral Mass Fixation on Postoperative Axial Pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 no preoperative lower limb palsy no lower limb paralysis that would impede the patient's ability to walk no addiction to drugs (except for smoking) that would interfere with pain assessment non-pregnancy absence of a severe concurrent illness that would interfere with the investigation of the cause of pain no obstructive cardiac disease no acute neck trauma patient's full consent to participate in the study age between 18 and 65 years fusion in the C3-C7 range no sickle cell disease in the patient no sensitivity to epinephrine and anesthetics no underlying cancer
Exclusion criteria:
 pregnancy a significant drop in lower limb force after the surgery that would impede the patient's ability to walk after the operation acute neck trauma any accompanying illness that would interfere with the investigation of the cause of pain any concurrent surgery outside the C3-C7 range infection at the surgical site up to one week after the operation age below 18 years and above 65 years a severe diagnosed psychiatric illness or a psychiatric illness that the patient is taking medication for or has a history of taking medication to treat if the patient has a gain If the patient undergoes simultaneous neck surgery through the anterior approach addiction to drugs (except for smoking) if the reason for the surgery is a tumor

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the block randomization approach, the intervention and control groups will be assigned, and the randomization sequence will be performed based on the website <https://www.sealedenvelope.com/simple-randomiser/v1/lists>. For this purpose, 60 coded packets will be prepared, 30 of which will contain the intervention of anesthesia and the other 30 will not. The treating physician and researcher will remain unaware of the content of the packet until the last moment, and the patient's packet will be opened during the operation, and the patient will be placed in one of the two groups based on that.

Blinding (investigator's opinion)
Double blinded

Blinding description
Sixty coded packets will be prepared, 30 of which will contain the intervention of anesthesia and the other 30 will not. The treating physician and researcher will remain unaware of the content of the packet until the last moment, and the patient's packet will be opened during the operation, and the patient will be placed in one of the two groups based on that. Additionally, the patient will remain unaware of which group they belong to until the end of the study. Finally, the two groups will be delivered to the statistical analyzer for analysis without the analyzer being informed of the group type for each code.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Shariati Hospital
Street address
University of Tehran Married Students Dormitory, Daneshju Blvd, Tehran-Karaj Highway, Tehran, Iran.
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Tehran
Postal code
1389939371
Approval date
2023-07-29, 1402/05/07
Ethics committee reference number
IR.TUMS.SHARIATI.REC.1402.075

Health conditions studied

1

Description of health condition studied

تنگی کانال گردن

ICD-10 code

M99.41

ICD-10 code description

Connective tissue stenosis of neural canal of cervical region

Primary outcomes

1

Description

Postoperative pain intensity

Timepoint

6 hours, 24 hours, 48 hours, and 1 week after surgery

Method of measurement

Numeric Rating Scale score

2

Description

amount of narcotic analgesic consumption

Timepoint

24 hours and 48 hours after surgery

Method of measurement

The dose of injected narcotic medication is recorded in milligrams in the documents included in the file during 24 and 48 hours after the end of the surgery

3

Description

type of analgesic used

Timepoint

24 hours and 48 hours after surgery

Method of measurement

Investigating the type of medication injected based on the documents included in the file during 24 and 48 hours after the end of the surgery

4

Description

The first time the patient walks after surgery

Timepoint

Up to 48 hours after surgery

Method of measurement

The duration from the end of surgery until the patient starts walking in the ward, as observed directly and asked from the patient

5

Description

The first time the patient requests pain medication.

Timepoint

Up to 48 hours after surgery

Method of measurement

The time from the end of surgery until the patient requests pain medication for pain relief, recorded in

hours with the help of patient questioning

6

Description

number of cervical fusion levels

Timepoint

At the end of the surgical procedure

Method of measurement

The number of cervical vertebrae that have screws inserted into them is recorded through direct observation of radiology images taken after the surgery

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group of 30 people receive 4 milligrams of dexamethasone and 15 cc of 0.5% bupivacaine (maximum injectable dose of bupivacaine for local injection is 175 milligrams) injected into each erector spinae plane muscle site at the end of the surgical procedure and throughout the surgical site where the skin incision is made, after washing and before closing the fascia. This injection is performed by the neurosurgeon performing the surgical procedure

Category

Treatment - Drugs

2

Description

Control group: A group of 30 people who will not receive this drug injection, instead, they will receive 16 cc of placebo (normal saline).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Mohammad Rostami Ravari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Web page address
<https://rmo.tums.ac.ir/main>

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Rostami Ravari
Position

Neurosurgery resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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 results and data of this study will be published honestly, accurately, and completely. Both negative and positive results, as well as budget sources, organizational affiliations, and conflicts of interest, if any, will be fully disclosed.

When the data will become available and for how long

The start of the data and results access period for the study will be one month after the publication of the results.

To whom data/document is available

The data will only be accessible to researchers employed at academic and scientific institutions and individuals who participated in this study.

Under which criteria data/document could be used

The use of the data from this study is only authorized for the purpose of improving patients' health.

From where data/document is obtainable

To access the data, you can contact the researcher of this project via email and submit a request to access the data. The email address is dmr.rostami@gmail.com, and the name of the researcher is Mohammad Rostami Ravari.

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

The requester must clearly state their purpose for accessing the data with sufficient documentation, and if it complies with ethical and scientific principles and helps improve patient health, the data from this study will be provided to them.

Comments