Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the Simultaneous Use of Topical Methylprednisolone and Topical Bupivacaine in the Retropharyngeal Space on the Incidence of Dysphagia Following Anterior Cervical Discectomy and Fusion (ACDF): A Single-Blind Clinical Trial

Protocol summary

Study aim

To determine the effect of simultaneous topical methylprednisolone and topical bupivacaine administration in the retropharyngeal space on the incidence of dysphagia after ACDF

Design

A phase 3 single-blind controlled clinical trial will be conducted on 60 patients. All patients who meet the inclusion criteria will be assigned to either the intervention or control group using a block randomization approach, with the randomization sequence generated through the website https://www.sealedenvelope.com/simple-randomiser/v1/lists. Accordingly, in the intervention group of 30 patients, a combination of 1 cc (40 mg) methylprednisolone and 10 cc (50 mg) of 0.5% bupivacaine will be administered into the retropharyngeal space after irrigation and before fascial closure.

Settings and conduct

Patients who are candidates for anterior cervical discectomy and fusion surgery at Shariati Hospital in Tehran will be enrolled and allocated to either the intervention or the control group. The patients will be blinded to their group assignment. Patients in the intervention group will receive an injection of the designated compound into the retropharyngeal space, whereas patients in the control group will not receive the injection

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing ACDF (up to 3 levels) between C2 and C7. Exclusion criteria: Age <18 or >65 years, oropharyngeal tumors, neurological or psychiatric disorders, acute cervical trauma, substance abuse, prior anterior cervical surgery, and pregnancy.

Intervention groups

In patients undergoing ACDF surgery, the intervention group will receive a local application of a combination of methylprednisolone and bupivacaine in the retrpharyngeal space, while the control group will not receive this combination.

Main outcome variables

Postoperative dysphagia severity, postoperative odynophagia severity, and duration of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250814066853N1**
Registration date: **2026-07-03, 1405/04/12**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-03, 1405/04/12**
Update count: **0**

Registration date

2026-07-03, 1405/04/12

Registrant information

Name

Sadegh Fallah delavar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 1000

Email address

sadegh.fd@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-06-22, 1405/04/01
Expected recruitment end date
2027-02-20, 1405/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Simultaneous Use of Topical Methylprednisolone and Topical Bupivacaine in the Retropharyngeal Space on the Incidence of Dysphagia Following Anterior Cervical Discectomy and Fusion (ACDF): A Single-Blind Clinical Trial

Public title
Evaluation of the effect of methylprednisolone and bupivacaine on dysphagia in anterior cervical discectomy and fusion surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for Anterior cervical discectomy and fusion surgery up to a maximum of three levels surgical levels between C2 and C7
Exclusion criteria:
Age under 18 or over 65 years Pregnancy Previous surgery in the anterior cervical region Neurologic and psychologic diseases Acute cervical truma Drug addiction Oropharyngeal tumors
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants who met the inclusion criteria and provided informed consent were randomly allocated to either the intervention or control group. Randomization was performed using block randomization with a 1:1 allocation ratio, and the unit of randomization was the individual patient. The random allocation sequence was generated using a computer-based random number generator through the website https://www.sealedenvelope.com/simple-randomiser/v1/lists. Accordingly, a total of 60 patients were randomly assigned to two equal groups of 30 patients each. To minimize allocation bias, the pre-generated random sequence was applied sequentially at the time of patient enrollment. In this study, only the patients were blinded to group allocation (single-blind), while the surgeon and the investigator were aware of the assigned intervention.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants are informed that they will be randomly assigned to one of the two groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Tehran University Campus, Imam Khomeini Boulevard, Daneshjoo Boulevard, Married Students' Residence, Building 104
City
Tehran
Province
Tehran
Postal code
1389939144
Approval date
2025-06-15, 1404/03/25
Ethics committee reference number
IR.TUMS.SHARIATI.REC.1404.042

Health conditions studied

1

Description of health condition studied
Cervical disc disorders
ICD-10 code
M50
ICD-10 code description
Cervical disc disorders

Primary outcomes

1

Description
Dysphagia severity after surgery
Timepoint
One and two days and one and two weeks after surgery
Method of measurement
Bazaz scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A combination of 1 cc (40 mg) of methylprednisolone (manufactured by Jabir Ibn Hayan Company) and 10 cc (50 mg) of 0.5% bupivacaine (manufactured by Exir Danesh Asia Company) will be administered into the retropharyngeal space after irrigation and before fascial closure.
Category
Prevention

2

Description
Control group: In the control group, the combination of methylprednisolone and bupivacaine used in the intervention group will not be administered.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Sadegh Fallah Delavar
Street address
Dr. Shariati Hospital, Dr. Ahmadi St., Jalal al-Ahmad Expressway, Tehran, Iran.
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1411713135
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Email
shariatihosp@tums.ac.ir
Web page address
https://shariati.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
Keshavarz Boulevard, Corner of Ghods Street, Central Organization of the University, Sixth Floor, Vice Presidency for Research and Technology
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Province
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Postal code
141765383761
Phone
+98 21 8163 3698
Fax
+98 21 8898 9664
Email
vcr@tums.ac.ir
Web page address
https://vcr.tums.ac.ir/
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
Sadegh Fallah delavar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
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Building 104 , Married Students' Residence, Daneshjoo Boulevard, Imam Khomeini Boulevard , Tehran University Campus,
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Sadegh Fallah delavar

Position

Resident

Latest degree

Medical doctor

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Person responsible for updating data

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Full name of responsible person

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Position

Resident

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The participants' data file will remain exclusively with the researcher for future analyses; however, the results obtained from the statistical data will be fully shared with all researchers in the form of a published article.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable