

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 retropharyngeal 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/lits>. 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

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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

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Dr. Shariati Hospital, Dr. Ahmadi St., Jalal al-Ahmad Expressway, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ramin Kordi

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Keshavarz Boulevard, Corner of Ghods Street, Central Organization of the University, Sixth Floor, Vice Presidency for Research and Technology

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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

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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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