

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Investigating the effectiveness of intraoperative topical steroids in preventing dysphagia and swallowing disorders in patients undergoing anterior cervical discectomy surgery with fusion

Protocol summary

Study aim

Investigating the effectiveness of intraoperative topical steroids in preventing dysphagia and swallowing disorders in patients undergoing anterior cervical discectomy surgery with fusion

Design

In a randomized block design, subjects are divided into two groups (total of 120) and then the medication is administered by the clinical caregiver with a specific code and provided to the researcher. The researcher assesses the patients using an examination and records the results based on the patient code.

Settings and conduct

Using the randomized block method, patients referred to Al-Zahra Hospital are divided into two groups, and then medication is administered by the clinical caregiver with a specific code and provided to the researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient must consent to participate in the study. The patient has undergone anterior discectomy with fusion. Exclusion criteria: Patients who have undergone surgery with traumatic, neoplastic, or infectious symptoms Patients who had previously received corticosteroids (6 months ago).

Intervention groups

Patients in the intervention group (n = 60) will be given depomedrol. 5 cc of depomedrol is required for each gelfoam. In fact, a 4 x 2 cm gelfoam will be completely soaked. Patients in the control group (n = 60) will be given an equivalent volume of saline solution at the same time points to receive placebo.

Main outcome variables

Dysphagia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221108056446N12**

Registration date: **2025-01-15, 1403/10/26**

Registration timing: **prospective**

Last update: **2025-01-15, 1403/10/26**

Update count: **0**

Registration date

2025-01-15, 1403/10/26

Registrant information

Name

Mehdi Mahmoodkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 686 3733

Email address

mahmoodkhani@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date

2025-05-22, 1404/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of intraoperative topical

	steroids in preventing dysphagia and swallowing disorders in patients undergoing anterior cervical discectomy surgery with fusion
Public title	Topical steroid during anterior cervical discectomy with fusion in preventing dysphagia
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion criteria: The patient must consent to participate in the study. The patient has undergone anterior discectomy with fusion. Exclusion criteria: Patients who have undergone surgery with traumatic, neoplastic, or infectious symptoms Patients who had previously received corticosteroids (6 months ago).
Age	No age limit
Gender	Both
Phase	2
Groups that have been masked	No information
Sample size	Target sample size: 120
Randomization (investigator's opinion)	Randomized
Randomization description	With the convenience sampling method, the referring individuals who are eligible for the study are randomly divided into two groups: case and control. In this study, the division of individuals is done using the four-way permutation block method. In this method, A represents the individual who receives the intervention and B represents the individual who is in the control group. Considering the four-way block, we give the AABB permutation code 0, the ABAB permutation code 1, ABBA code 2, BAAB code 3, BBAA code 4, and BABA codes 5 to 9. Then, using the random number table, we randomly select a starting point and then consider the numbers in rows or columns. Considering the order of the numbers in the table, we assign the corresponding permutation to each number we encounter. Finally, 120 people will be divided into two groups.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	

<u>1</u>	
Ethics committee	
Name of ethics committee	Esfahan University of Medical Sciences
Street address	Hazar Jarib Street, Azadi Square
City	Esfahan
Province	Isfahan
Postal code	8174673461
Approval date	2024-12-24, 1403/10/04
Ethics committee reference number	IR.MUI.MED.REC.1403.404
Health conditions studied	
<u>1</u>	
Description of health condition studied	Cervical disc
ICD-10 code	M43.22
ICD-10 code description	Fusion of spine, cervical region
Primary outcomes	
<u>1</u>	
Description	Dysphagia
Timepoint	Data is collected before surgery and at 1 day, 2 days, 1 week, 2 weeks, 1 month, 3 months, 6 months, and 1 year after surgery.
Method of measurement	Patient examination
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: For patients in the intervention group (60 patients), depomedrol is administered. 5 cc of depomedrol is required for each gelfoam. In fact, a gelfoam measuring 4 x 2 cm is completely soaked.
Category	Prevention
<u>2</u>	
Description	Control group: For patients in the control group (60

patients), normal saline is administered. 5 cc of normal saline is required for each gelfoam. In fact, a gelfoam measuring 4 x 2 cm is completely soaked.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Shafiei

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

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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

Esfahan University of Medical Sciences

Proportion provided by this source

1

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**

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Shafiei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact**

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Latest degree

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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