Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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. Exclution 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

1

Ethics committee
Name of ethics committee
Esfahan University of Medical Sciences
Street address
Hazar Jarib Street, Azadi Square
City
Esfahan
Province
Isfehan
Postal code
8174673461
Approval date
2024-12-24, 1403/10/04
Ethics committee reference number
IR.MUI.MED.REC.1403.404

Health conditions studied

1

Description of health condition studied
Cervical disc
ICD-10 code
M43.22
ICD-10 code description
Fusion of spine, cervical region

Primary outcomes

1

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

1

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

2

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
Street address
Hazar Jarib Street, Azadi Square
City
Esfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
mui@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Asgari
Street address
Hazar Jarib Street, Azadi Square
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 0048
Email
mui@mui.ac.ir
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
Street address
Sofeh Street
City
Esfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
mui@mui.ac.ir

Person responsible for scientific 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
Street address
Sofeh Street
City
Esfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
mui@mui.ac.ir

Person responsible for updating data

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
Street address
Sofeh Street
City
Esfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
mui@mui.ac.ir

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