

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

#### 1

##### 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

#### 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**

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**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

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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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mehdi Shafiei

**Position**

Assistant Professor

**Latest degree**

Specialist

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**Person responsible for updating data****Contact**

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

Neurosurgery

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8174673461

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+98 31 3668 0048

**Email**

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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