

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Evaluation of the effectiveness of comparing short and long-term use of cervical collar after anterior cervical discectomy on vertebral fusion and its outcome

#### Protocol summary

##### Study aim

Determining the effectiveness of duration of cervical collar use after anterior cervical discectomy on vertebral fusion and its outcome

##### Design

This study is a clinical trial that is performed in parallel groups without blinding on 70 patients who underwent anterior cervical disc surgery.

##### Settings and conduct

Among patients with unilateral or bilateral neck or upper limb pain or upper extremity who are candidates for anterior cervical discectomy using cage and allograft in Al-zahra Hospital, half of the patients were randomly nominated for closing cervical collar for two weeks (control group). And the other half are randomly selected as candidates for closing cervical collar for two months (case group) and are included in the study. The type of collar used in all Philadelphia patients and the meaning of collar in this study is the same as Philadelphia collar.

##### Participants/Inclusion and exclusion criteria

inclusion criteria Patient with a single cervical disc herniation The need for surgical intervention that requires the release of pressure from the spinal cord No history of underlying diseases such as diabetes and neuropathy and heart disease No smoking and addiction Satisfaction to participate in the study exclusion criteria Patients who have previously undergone cervical spine surgery. Age over 60 years. Patients who have previously undergone cervical spine surgery. Patients who need fixation with screws and plates. Patients who are undergoing posterior neck surgery or need it in the future.

##### Intervention groups

Close the cervical collar for two months

##### Main outcome variables

During the follow-up period, patients are evaluated for the rate of fusion on the radiograph, the degree of

improvement of symptoms and axial pain, and the degree of collar compliance.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210406050867N1**

Registration date: **2021-09-28, 1400/07/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-09-28, 1400/07/06**

Update count: **0**

##### Registration date

2021-09-28, 1400/07/06

##### Registrant information

##### Name

Mehrdad Larry

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3669 2255

##### Email address

mehrdad.larry@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-23, 1400/06/01

##### Expected recruitment end date

2022-08-23, 1401/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effectiveness of comparing short and long-term use of cervical collar after anterior cervical discectomy on vertebral fusion and its outcome

**Public title**  
Cervical collar after anterior discectomy surgery of a neck surface

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patient with a single cervical disc herniation The need for surgical intervention that requires the release of pressure from the spinal cord. No history of underlying diseases such as diabetes and neuropathy and heart disease No smoking and addiction Satisfaction to participate in the study  
**Exclusion criteria:**  
Patients who need surgery for more than one cervical disc herniation. Patients who have previously undergone cervical spine surgery. Age over 60 years. Patients who need fixation with screws and plates. Patients who are undergoing posterior neck surgery or need it in the future. Incidence of surgical complications during surgery (root injury, thecal sac rupture, etc.)

**Age**  
From **20 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **70**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Random function of Excel software based on patient file number will be used for randomization. Patients with a cervical disc were entered into Excel based on the file number and divided into case and control groups based on the random button. In total, there were two groups of 35 people. By entering the file number in Excel program, then the random number is selected from the data analysis command. This study has 2 groups that can be numbered from 1 to 2, respectively. We also want to have 70 people in each group. As a result, sequences 1 to 2 should be repeated 100 times each time. It is clear that the repetition of each number occurs once in each group, so select 1 for repeating each number and 35 for repeating the sequence. In this way, 70 units will be produced.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Isfahan University of Medical Sciences  
**Street address**  
Isfahan University of Medical Sciences, Hezar Jerib St., Shiraz Gate  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Approval date**  
2021-03-17, 1399/12/27  
**Ethics committee reference number**  
IR.MUI.MED.REC.1399.1186

## Health conditions studied

**1**

**Description of health condition studied**  
Symptomatic one level cervical disc herniation

**ICD-10 code**  
M50

**ICD-10 code description**  
Cervical disc disorders

## Primary outcomes

**1**

**Description**  
the amount of fusion on the radiograph

**Timepoint**  
At the time of referral, two weeks later and two months later

**Method of measurement**  
Fusion criteria in radiography

**2**

**Description**  
Healing axial pain

**Timepoint**  
At the time of referral, two weeks later and two months later

**Method of measurement**

pain scale and anesthesia

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Candidate for collar closure for two months-Patients after Discectomy surgery and cervical implantation with cage, after transferring to the ward, except in the supine position (sitting, standing and moving) continuously use the collar neck.

#### Category

Treatment - Devices

### 2

#### Description

Control group: Candidate for collar closure for two weeks

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Al-zahra Hospital

##### Full name of responsible person

Mehdi Shafiei

##### Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 0048

##### Email

Mehdishafiei82@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjuye Javanmardi

##### Street address

Isfahan University of Medical Sciences, hezar jarib S.T

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 0048

##### Email

research@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

Isfahan University of Medical Sciences, Hezar Jarib St.,

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##### Province

Isfahan

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+98 31 3668 0048

##### Email

Mehdishafiei82@gmail.com

## 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

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**Phone**

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**Email**

Mehdishafiei82@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mehrdad Larry

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurosurgery

**Street address**

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**Email**

mehrdad.larry@gmail.com

**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