

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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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

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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

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Isfahan University of Medical Sciences, Hezar Jarib St.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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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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