Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Isfehan

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 transfering 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
Isfehan
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
Isfehan
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.,
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+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
Street address
Isfahan University of Medical Sciences, Hezar Jarib St.,
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
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
Isfahan University of Medical Sciences, Hezar Jarib St.,
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
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