

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of cervical collar duration on fusion outcomes after posterior cervical fusion surgery: a randomized clinical trial

Protocol summary

Study aim

This randomized controlled clinical trial aims to investigate the effect of cervical collar duration on vertebral fusion outcomes after posterior cervical fusion surgery (PCF).

Design

Randomized parallel-group interventional study with blinded radiographic outcome assessment.

Settings and conduct

The trial will be conducted in the neurosurgery department of Dezful University of Medical Sciences hospitals. Random allocation will be computer-generated. Ethical approval has been obtained from the university ethics committee (code: IR.DUMS.REC.1404.008, approval date: May 12, 2025).

Participants/Inclusion and exclusion criteria

Sixty patients aged ≤ 60 years who are candidates for PCF and meet inclusion criteria will be enrolled. Exclusion criteria include previous cervical spine surgery, major comorbidities such as uncontrolled diabetes or cardiac disease, and smoking or narcotic use. All participants will provide written informed consent.

Intervention groups

Participants will be randomly assigned into two parallel groups: Group A will use a Philadelphia cervical collar continuously for six weeks after surgery, and Group B will use the collar for twelve weeks.

Main outcome variables

The primary outcome is the rate of successful cervical fusion at six months post-surgery, assessed radiographically using the fusion assessment scale. Secondary outcomes include changes in neck pain (VAS), neck disability index (NDI), neurological status, and collar-related complications.

General information

Reason for update

Acronym

Cervical-Collar-PCF Trial

IRCT registration information

IRCT registration number: **IRCT20251020067698N1**
Registration date: **2025-11-12, 1404/08/21**
Registration timing: **prospective**

Last update: **2025-11-12, 1404/08/21**

Update count: **0**

Registration date

2025-11-12, 1404/08/21

Registrant information

Name

Sara Kord

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 937 674 1216

Email address

bahare.kord132@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-03-21, 1405/01/01

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of cervical collar duration on fusion outcomes after posterior cervical fusion surgery: a randomized clinical trial

Public title

Evaluating the appropriate duration of cervical collar use after cervical spine fusion surgery

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients are candidates for posterior cervical fusion (PCF) surgery. Patient age is between 18 and 60 years. Patient has no prior cervical spine surgery. Patient has no severe comorbidities. Patient is a non-smoker and does not use illicit drugs. Patient can understand the informed consent form. Patient provides written informed consent.

Exclusion criteria:

Patient has previous cervical spine surgery. Patient age is under 18 years. Patient requires anterior fixation . Patient has uncontrolled diabetes. Patient has advanced cardiac disease. Patient has peripheral neuropathy. Patient is pregnant . Patient uses chronic corticosteroids. Patient age is over 60 years. Patient requires anterior plating. Patient is breastfeeding. Patient uses immunosuppressive drugs.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple randomization. The unit of randomization is individual. No stratification is applied. The randomization tool is SPSS software version 24 using a random number generator. Sequence generation: After patient enrollment and consent, the unique ID is entered into SPSS; even numbers are assigned to the 6-week group, odd numbers to the 12-week group. Allocation ratio is 1:1. Allocation concealment is achieved using sequentially numbered, opaque, sealed envelopes (SNOSE). The allocation list is prepared by an independent research nurse and placed in envelopes. Envelopes are stored in a locked cabinet. The envelope is opened in the presence of the patient by the research nurse. The investigator, surgeon, and patient remain blinded to the allocation until the envelope is opened.

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 Dezful University of Medical Sciences

Street address

Khuzestan Province, Dezful City, Ayatollah Ghazi Boulevard, Dezful Grand Hospital, Department of Neurosurgery, Dezful University of Medical Sciences

City

Dezfoul

Province

Khuzestan

Postal code

6461883835

Approval date

2025-05-12, 1404/02/22

Ethics committee reference number

IR.DUMS.REC.1404.008

Health conditions studied**1****Description of health condition studied**

Cervical vertebral fusion following posterior cervical fusion surgery (PCF)

ICD-10 code

M50.2

ICD-10 code description

Other cervical disc displacement

Primary outcomes**1****Description**

Rate of successful cervical vertebral fusion after posterior cervical fusion surgery, based on radiographic findings and fusion assessment criteria

Timepoint

Six months after surgery

Method of measurement

Radiographic evaluation (X-ray or CT scan) by a blinded assessor using the vertebral fusion assessment scale

Secondary outcomes

empty

Intervention groups**1****Description**

Patients in this group use a Philadelphia Collar for 6 weeks after posterior cervical fusion surgery. The collar is rigid and standard model. Manufacturer: Iran Medical Equipment Co. or equivalent (Aspen/Össur). The collar is worn 24 hours daily except during bathing. Training on collar application and adjustment is provided by the research nurse on postoperative day 1. Weekly follow-up by the research nurse to ensure compliance and check for skin complications.

Category

Other

2**Description**

Intervention group: Patients in this group use a Philadelphia Collar for 12 weeks after posterior cervical fusion surgery. The collar is rigid and standard model. Manufacturer: Iran Medical Equipment Co. or equivalent (Aspen/Össur). The collar is worn 24 hours daily except during bathing. Training on collar application and adjustment is provided by the research nurse on postoperative day 1. Weekly follow-up by the research nurse to ensure compliance and check for skin complications.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ganjavian Hospital

Full name of responsible person

Sara Kord

Street address

Ganjavian Hospital, Next to the Traffic Police Department, Azadegan Blvd., Dezfoul

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Dezfoul University of Medical Sciences

Full name of responsible person

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http://www.dums.ac.ir/

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Vice Presidency of Education, Research, and Technology, Dezfoul University of Medical Sciences

Proportion provided by this source

100

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**

Dezfoul University of Medical Sciences

Full name of responsible person

Sara Kord

Position

Faculty Member, Faculty of Paramedicine, Dezfoul University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

nursing

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Dezful University of Medical Sciences

Full name of responsible person

Sara Kord

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Study Protocol: Investigating the Effectiveness of Cervical Collar Duration on Cervical Spine Fusion Outcomes Following Posterior Cervical Fusion Surgery" – This is the full research protocol document, including background, objectives, methodology, ethical considerations, and statistical plan (approximately 50 pages, in PDF format).

When the data will become available and for how long

Available starting from the date of trial completion and primary results publication (expected 12-18 months after study initiation in 1403/2024), and indefinitely (no expiration).

To whom data/document is available

Available to researchers, clinicians, and academic institutions worldwide upon reasonable request; not for commercial use.

Under which criteria data/document could be used

Use permitted for non-commercial scientific research, meta-analyses, or educational purposes; must cite the original study and comply with data protection laws (e.g., GDPR equivalents). Prohibited for patient re-identification or proprietary development.

From where data/document is obtainable

Obtainable from the IRCT registry (irct.ir), the university's research repository (Dezful University of Medical Sciences website), or via email request to the principal investigator.

What processes are involved for a request to access data/document

Submit a formal request via email to the principal investigator (sara.kord@dezfulums.ac.ir) including purpose, credentials, and intended use; approval by the university ethics committee within 2-4 weeks; access granted via secure link (e.g., Google Drive or institutional FTP).

Comments

Sharing promotes transparency and reproducibility; updates to the protocol will be versioned and shared if amendments occur. Contact: +98 61 42429731.