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
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Iran (Islamic Republic of)
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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
Khouzestan
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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Dezfoul University of Medical Sciences

Full name of responsible person
Reza Fathi

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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, Dezful 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, Dezful University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
nursing

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Person responsible for scientific inquiries

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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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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.