Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of specific and routine therapeutic exercises after cervical spine disc herniation surgery on functional disability, pain and neck muscle morphology

Protocol summary

Study aim

Comparison of specific and routine therapeutic exercise after cervical spine disc herniation surgery on functional disability, pain and neck muscle morphology.

Design

The study is a double-blind parallel randomized controlled clinical trial, with a control group and an experimental group, which is conducted on 60 patients. Random Allocation software was used for randomization.

Settings and conduct

This study will be conducted in the biomechanics laboratory of Rehabilitation Faculty of Babol University of Medical Sciences, on patients who have undergone anterior approach surgery due to cervical disc herniation. Two methods of routine and specific therapeutic exercise are examined and compared. The study is double-blind, so that both the patient and the person who evaluates the results are unaware of which group the respective patient belongs to.

Participants/Inclusion and exclusion criteria

1- aged 46 to 70 years old; 2- Continuous and treatment-resistant pain caused by cervical spine disc herniation for at least 2 consecutive months; 3- Clinical findings confirmed by MRI; 4- Patients who underwent surgery with an anterior approach; 5- Weakness of limbs or upper limbs before surgery.

Intervention groups

The control group includes patients who receive usual care after surgery. The intervention group includes patients who receive specific therapeutic exercises in addition to usual care.

Main outcome variables

The main outcomes include: functional disability; pain intensity; range of motion and morphological changes (cross-sectional area and thickness) of the cervical longus colli and multifidus muscles.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221019056245N2**
Registration date: **2023-08-20, 1402/05/29**
Registration timing: **prospective**

Last update: **2023-08-20, 1402/05/29**
Update count: **0**

Registration date

2023-08-20, 1402/05/29

Registrant information

Name

Khodabakhsh Javanshir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3233 6419

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2023-12-01, 1402/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of specific and routine therapeutic exercises after cervical spine disc herniation surgery on functional disability, pain and neck muscle morphology

Public title
Comparison of routine and specific therapeutic exercise after cervical spine disc herniation surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged 46 - 70 years old Continuous and treatment-resistant pain caused by cervical spine disc herniation for at least 2 months Clinical findings confirmed by MRI Weakness of upper limb or limbs before surgery Patients who underwent surgery with an anterior approach

Exclusion criteria:
History of previous surgery Pain greater than score 8 after surgery based on VAS Need for re-surgery Surgery caused by systemic diseases Surgery due to fracture Surgery caused by infection Decreased range of motion due to osteophyte and fusion of vertebrae

Age
From **46 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, eligible participating patients, after receiving informed consent, according to the block randomization protocol (produced by Random Allocation Software) were divided into one of two control and intervention groups with a ratio of 1:1 and in blocks of 6 will be allocated, in such a way that the researcher cannot predict in which intervention group the next person will be placed. The codes will be placed inside the opaque envelopes, and with the arrival of each new person, the envelope will be opened and the person's belonging to the relevant group will be determined. Allocation concealment In order to hide the random allocation, the codes created by the software will be placed in opaque envelopes so that it is not clear which group the next person will be placed in.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted in a double-blind manner. In this way, both the patients and the evaluator (physiotherapist colleague) will be completely unaware of which group the patient belongs to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

Street address
Ganj afrooz St.

City
Babol

Province
Mazandaran

Postal code
4717647745

Approval date
2023-08-01, 1402/05/10

Ethics committee reference number
IR.MUBABOL.REC.1402.063

Health conditions studied

1

Description of health condition studied
Neck surgery due to cervical disc herniation

ICD-10 code
M50.3

ICD-10 code description
Other cervical disc degeneration

Primary outcomes

1

Description
Functional ability

Timepoint
Before the intervention and after the intervention

Method of measurement
Neck Pain Disability Questionnaire

2

Description
morphology of the deep cervical muscles

Timepoint
Before the intervention and after the intervention

Method of measurement
By the ultrasonography device

Secondary outcomes

1

Description
Pain intensity
Timepoint
Before the intervention and after the intervention
Method of measurement
Pain intensity Visual Analogue Scale

Intervention groups

1

Description
Intervention group: The intervention group will perform routine care in addition to specific exercises for eight weeks, three times a week for forty minutes each time.
Category
Rehabilitation

2

Description
Control group: Patients in the control group will receive training such as daily care, walking and maintaining posture, which will be provided to them in the form of an educational brochure, for 8 weeks. Once a week, therapist will communicate with patients by phone.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Yhayanahad hospital
Full name of responsible person
Payam saadat
Street address
Shahid mostafa khomeini St., modarres St., Babol
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mehdi Rajabnia
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info@mubabol.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Khodabakhsh Javanshir
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
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Person responsible for scientific inquiries

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Position
Associate Professor

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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
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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available