

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of routine physiotherapy with and without stabilization exercise on pain, functional disability, neck range of motion and dimensions of the cervical multifidus and longus colli muscles in patients with unilateral chronic cervical radiculopathy:

Protocol summary

Study aim

Effect of routine physiotherapy treatment with and without stabilization exercise

Design

50 patients with unilateral cervical radiculopathy

Settings and conduct

Hospitals of the University of Social Welfare and Rehabilitation Performing therapeutic interventions and comparing their effect

Participants/Inclusion and exclusion criteria

Patients with unilateral chronic radicular neck pain of both males and females aged 25-60 years with involvement in lower cervical vertebrae Patients with unilateral chronic radicular neck pain, which the physician approved was diagnosed by clinical examinations, MRI imaging and electrodiogenesis tests. Patients with unilateral chronic radiculopathy who had symptoms for at least 3 months. Incidence of symptoms in the neck and arm areas include: pain intensification with neck movements, sensory changes, motor weakness, reduction of deep tendon reflexes

Intervention groups

The experimental group received a routine physical and neck stabilization exercises Control group received routine physiotherapy

Main outcome variables

Pain intensity; Neck disability index; Range of motion; Deep cervical muscles dimensions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160511027845N1**

Registration date: **2017-12-27, 1396/10/06**

Registration timing: **retrospective**

Last update: **2017-12-27, 1396/10/06**

Update count: **0**

Registration date

2017-12-27, 1396/10/06

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4489 6279

Email address

so.amiri@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of routine physiotherapy with and without stabilization exercise on pain, functional disability, neck range of motion and dimensions of the cervical multifidus and longus colli muscles in patients with unilateral

chronic cervical radiculopathy:

Public title
physical therapy treatment of cervical radiculopathy patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
1) patients with unilateral chronic cervical rediculopathy, both male and female, age between 25-60 years old, with involvement in lower cervical vertebrae. 2) Patients with unilateral chronic radicular neck pain, that physician have confirmed this disorder by clinical examination, MRI imaging and electrodiagnostic tests. 3) patients with unilateral chronic radicular neck pain that they have been at least 3 months of the onset of symptoms. 4) the intensity of pain in the neck and arm regions is between 3 to 7 of visual analogue scale pain score, and with at least one of the following; pain aggravated by neck movements, changes in sensory, motor weakness, loss of deep tendon reflexes. 5) patients who have a desire to participate in the study.
Exclusion criteria:
1) chronic non-specific neck pain and Whiplash. 2) bilateral cervical radiculopathy. 3) previous surgery of cervical or thoracic spine. 4) patients with myelopathy, peripheral neuropathy, damage to the shoulder joint and Thoracic Outlet Syndrome. 5) evidence of involvement of the central nervous system such as Hoffman sign, Babinski, clonus. 6) pain in the neck region due to arthritis, cancer and immune system such as rheumatoid arthritis. 7) presence of congenital abnormalities in the spine known as scoliosis, torticollis in childhood. 8) postural abnormalities of spine such as Forward Head Posture, hyperkyphosis. 9) Compression fracture caused by osteoporosis, stenosis and spondylolysis or spondylolisthesis. 10) having systemic diseases or general health problems such as pulmonary diseases, myopathy, fibromyalgia, cancer, spinal tuberculosis. 11) wounds in neck region. 12) primarily temporomandibular disorders. 13) visual and hearing impairments. 14) Pregnancy. 15) specific treatment for neck and shoulder during the last 3 months.

Age
From **25 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
• Investigator

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization

Blinding (investigator's opinion)
Single blinded

Blinding description

Participants Assessor

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
University of Social Welfare and Rehabilitation Sciences
Street address
kodakyar Ave., daneshjo Blvd.,Evin, tehran
City
tehran
Province
Tehran
Postal code
1985713834
Approval date
2015-09-02, 1394/06/11
Ethics committee reference number
IR.USWR.REC.1394.294

Health conditions studied
1
Description of health condition studied
cervical radiculopathy
ICD-10 code
M50.1
ICD-10 code description
Cervical disc disorder with radiculopathy

Primary outcomes
1
Description
disability
Timepoint
before and after intervention
Method of measurement
neck disability index

2
Description
pain intensity
Timepoint
before and after intervention
Method of measurement
visual analogue scale

3

Description

range of motion

Timepoint

before and after intervention

Method of measurement

goniometer

4

Description

cervical muscles dimensions

Timepoint

before and after intervention

Method of measurement

ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description

intervention: neck stabilization exercise and routine
physiotherapy control: routine physiotherapy

Category

Rehabilitation

Recruitment centers

1

Recruitment center**Name of recruitment center**

Rofeideh hospital

Full name of responsible person

Somayeh Amiri Arimi

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Nemati Alley, Shahid baradaran soleimani Ave,
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amiri.somayeh88@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

Somayeh AmiriArimi

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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

University of social welfare and rehabilitation 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**

University of Social Welfare and Rehabilitation
Sciences

Full name of responsible person

somayeh amiri arimi

Position

physiotherapy PhD student

Latest degree

Master

Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some of the data, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

What kind of analysis is allowed on the delivered data, whether the use of the documentation is allowed or what other mechanisms will govern it.

From where data/document is obtainable

Email along with the names and addresses of individuals

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

According to working conditions about two months

Comments

Person responsible for updating data

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work**Street address**

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