Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)
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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
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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, Gheitariyeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
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Somayeh AmiriArimi
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kodakyar Ave., daneshjo Blvd.,Evin, Tehran
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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
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Person responsible for updating data

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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