Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Control trial of the effect of ergonomic latex pillow on pain and disability, range of motion, cervical flexor muscles endurance and head and neck posture in patients with cervical spondylosis

Protocol summary

Summary

The aim of this study is to investigate the effect of ergonomic latex pillow in patients with cervical spondylosis. This study is randomized control trial, single center and single blinded. Inclusion criteria: cervical spondylosis patients. Exclusion criteria: Trauma or disease affecting the cervical and cervicothoracic spine in the preceding year or a history of cervical surgery; Any change (increase or decrease) in head and neck support or people who use more than one pillow; Subjects normally using no pillow or anything other than a conventional pillow (which is common in Iranian culture like feather or cotton pillow) or if they have a history of using a cervical ruff or pillow (medical pillow); Subjects who received physiotherapy for neck pain during last three months; Wearing collar; Spinal cord canal stenosis. Sample size of the population is consisted of 42 patients. Subjects are divided into 2 groups that intervention group will receive ergonomic latex pillow and physiotherapy while control group will receive only physiotherapy for 4 weeks. Primary outcome measures: short cervical flexor muscles endurance, craniovertebral angle, pain, range of motion, disability. Secondary outcome measures: cervical extensor muscles endurance and the amount of satisfaction from ergonomic latex pillow.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014021916643N1**
Registration date: **2016-12-28, 1395/10/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-12-28, 1395/10/08

Registrant information

Name
Behshid Farahmand
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 2222 0947
Email address
farahmand.b@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Iran University of Medical Sciences

Expected recruitment start date

2017-01-17, 1395/10/28

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Control trial of the effect of ergonomic latex pillow on pain and disability, range of motion, cervical flexor muscles endurance and head and neck posture in patients with cervical spondylosis

Public title

The effect of ergonomic latex pillow on neck arthrosis

treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: people at the age of 30 to 60 year; Reporting a chronic and/or dull pain in the neck, with or without a radicular pain through the upper limbs; Grade 2 and 3 cervical spondylosis with at least two out of four of the following radiographic changes in the cervical region: Intervertebral disc space narrowing; Sclerosis of subchondral bone; Osteophyt formation between adjacent vertebral bodies or articular facets; The narrowing of the space between articular processes (facet joints); Positive compression and distraction test; Score ≥ 2 of 10 in Numerical Pasin Rating Scale (NPRS); Score ≥ 20% in Neck Disability Index (NDI) questionnaire. Exclusion criteria: Other non-specific neck pain lesions, acute neck strain, postural neck ache, or whiplash; Metabolic diseases, Paget's disease, osteoporosis, gout, or pseudo-gout; Inflammatory disease—rheumatoid arthritis, ankylosing spondylitis, or polymyalgia rheumatic; Infections—osteomyelitis or tuberculosis; tumors; Fibromyalgia and psychogenic neck pain; Temporomandibular joint surgery or disorder; Trauma or disease affecting the cervical and cervicothoracic spine in the preceding year or a history of cervical surgery; Spinal cord canal stenosis; Congenital anomalies involving the spine (cervical, thoracic, lumbar and scoliosis); Pregnancy or breast-feeding; Persistent respiratory difficulties over the last 5 years that have necessitated absence from work, have required long-term medication, or have interfered with daily activities; Recurrent middle ear infections over the last 5 years or any hearing impairment requiring the use of a hearing aid; Any change (increase or decrease) in head and neck support or people who use more than one pillow; Patients who don't complete a 12-sessions therapeutic period, or follow up evaluation; Subjects normally using no pillow or anything other than a conventional pillow (which is common in Iranian culture like feather or cotton pillow) or if they have a history of using a cervical ruff or pillow (medical pillow); Subjects who received physiotherapy or manipulation because of the neck pain during last three months; Wearing collar.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

closed pockets

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Shahid Chamran and Sheikh Fazlolah Junction, Hemmat Highway, Tehran

City

Tehran

Postal code

Approval date

2016-02-15, 1394/11/26

Ethics committee reference number

IR.IUMS. REC. 1394.9311502004

Health conditions studied

1

Description of health condition studied

cervical spondylosis

ICD-10 code

M47.8

ICD-10 code description

arthrosis or osteoarthritis of spine degeneration of facet joints

Primary outcomes

1

Description

range of motion

Timepoint

preintervention and post intervention

Method of measurement

inclinometer

2

Description

The amount of craniovertebral angle

Timepoint

Preintervention and post intervention

Method of measurement

Photo will be taken from patient and then the photo will be entered into the Adobe Acrobat Professional and craniovertebral angle will be calculated

3

Description
the amount of cervical short flexor muscles endurance
Timepoint
preintervention and post intervention
Method of measurement
the subject lying supine on bed then he/she gets his/her head up meanwhile retracting chin. The time of maintaining of this position is calculated by stop watch.

4

Description
Pain.
Timepoint
Before intervention, 1, 2 and 3 weeks later when intervention was applied and finally post intervention when treatment was done.
Method of measurement
Numerical Pain Rating Scale (The patient scores).

5

Description
The amount of disability caused by neck pain.
Timepoint
Before intervention, 1, 2 and 3 weeks later when intervention was applied and finally post intervention when treatment was done.
Method of measurement
Persian translation of Neck Disability Index questionnaire.

Secondary outcomes

1

Description
the amount of cervical extensor muscles endurance
Timepoint
preintervention and post intervention
Method of measurement
The subject lying prone on bed with their head and neck initially supported over the end while a 105 gr wheight suspended from his/her head then he/she extends his/her neck. The time of maintaining of this position is calculated by stop watch.

2

Description
The amount of satisfaction from ergonomic latex pillow
Timepoint
post intervention
Method of measurement
self-made questionnaire

Intervention groups

1

Description
Intervention group: physiotherapy + ergonomic latex pillow. Patients in this group sleep on ergonomic latex pillow for 4 weeks and will receive physiotherapy 3 sessions a week (12 sessions) for 30-45 minutes.
Category
Lifestyle

2

Description
Control group: physiotherapy + his/her usual pillow. Patients in this group sleep on their usual pillow for 4 weeks and will receive physiotherapy 3 sessions a week (12 sessions) for 30-45 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Ali Amiri; Physiotherapy PhD; Assistant Professor
Street address
Rasool Akram Hospital, next to Mansouri St, Niyayesh St, Sattarkhan St, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyed Ali Javad Moosavi, Research Vice Chancellor of Iran University of Medical Sciences.
Street address
Iran University of Medical Sciences, Chamran and Sheikh Fazlolah Junction, Hemmat Highway, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty

Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Behshid Farahmand
Position
Master of science/lecturer/ Orthotics and Prosthetics Faculty member
Other areas of specialty/work
Street address
Rehabilitation Faculty, Shahnazari St., Mirdamad Blv, Tehran
City
Tehran
Postal code
Phone
+98 21 2222 8051
Fax
Email
farahmandb1@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Fatemeh Fazli
Position
BS in orthotics and prosthetics
Other areas of specialty/work
Street address
Rehabilitation Faculty, Shahnazari St., Mirdamad Blv, Tehran
City
Tehran
Postal code
Phone
+98 21 2222 8051
Fax
Email
fatemehfazli89@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Fatemeh Fazli
Position
BS in orthotics and prosthetics
Other areas of specialty/work
Street address
Rehabilitation Faculty Shahnazari St., Mirdamad Blv, Tehran
City
Tehran
Postal code
Phone
+98 21 2222 8051
Fax
Email
fatemehfazli89@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty