

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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Name of organization / entity

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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 Pain Rating Scale (NPRS); Score $\geq 20\%$ 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 Fazlollah 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

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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