Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of sustained traction with Over-the-door home traction unit and Air neck traction device on neck pain, range of motion and disability level in cervical osteoarthritis.

Protocol summary

Summary

The aim of this study is to compare the effect of sustained traction by 'Over-the-door home traction unit' and 'Air neck traction device' on neck pain, range of motion and disability level in cervical osteoarthritis. The patients randomly will be assigned to two groups. Total sample is determined 26 cases and will be chosen from the patients with cervical osteoarthritis aged from 30-70 and with more or equal to 2 neck pain grade and the positivity of 'Compression & Distraction' test. The patients with the history of neck surgery or trauma, Grade 4 osteoarthritis and complications like rheumatoid arthritis and osteoporosis will be excluded from the study. Similar physical treatments will be received in both group in each session including common physiotherapy modalities such as hot pack, TENS, Ultrasound therapy and exercises. In the end of each session, first group of patients will be treated by the “Over-the-door home traction unit” and the second group will be treated by "Air neck traction device". Treatment intervention lasted 10 sessions (2 weeks) for each individual and the intensity of pain, range of motion and disability level will be measured in the beginning of the first session and in the end of the last session.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081118762N1**
Registration date: **2014-10-05, 1393/07/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-10-05, 1393/07/13

Registrant information

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Mojtaba Kamyab
Name of organization / entity
Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2014-11-21, 1393/08/30

Expected recruitment end date

2015-02-19, 1393/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of sustained traction with Over-the-door home traction unit and Air neck traction device on neck pain, range of motion and disability level in cervical osteoarthritis.

Public title

The effect of traction on cervical osteoarthritis symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 30-70 year-old; Chief complaint:

Cervical pain with or without any upper limb symptoms; Grade 1-3 osteoarthritis diagnosis from radio-graphs; Obtaining more or equal to 10% points in “Neck Disability Index” Questionnaire; More or equal to 2 points from 10 in “Numerical Pain Rating Scale”; Positive result from “Cervical Distraction & Compression” test. Exclusion criteria: History of cervical or upper thoracic(T1-T6) trauma; History of cervical surgery; Patients with severe cervical osteoarthritis (Grade 4) diagnosis based on radio-graphs; Spinal cord canal stenosis; non-skeletal symptoms; History of cervical spine fracture or sever vertebral osteoporosis; Rheumatoid arthritis; Visible congenital deformity of cervical spine; dysfunction of vertebral artery; Pregnancy; History of failed traction treatment; Considering any cervical physical therapies in the recent last 6 weeks.

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Commettee of Iran University of Medical Sciences

Street address
Between the cross-road of Sheykh Fazlolah and Shahid Chamran, Shahid Hemmat Highway

City
Tehran

Postal code

Approval date
2014-06-23, 1393/04/02

Ethics committee reference number
105/1433/93/د

Health conditions studied

1

Description of health condition studied
Cervical arthrosis

ICD-10 code
M47

ICD-10 code description
arthrosis of spine

Primary outcomes

1

Description
Neck pain

Timepoint
Before of first treatment session and in the end of last session

Method of measurement
Mean of total score- Numerical pain rating scale

2

Description
Cervical range of motion

Timepoint
Before of first treatment session and in the end of last session

Method of measurement
Inclinometer-Degree

3

Description
Neck disability index

Timepoint
Before of first treatment session and in the end of last session

Method of measurement
percent of total score-Neck disability index questioner

4

Description
Pain relife drug and Non-steroidal anti-inflammatory drug

Timepoint
Before of first treatment session and in the end of last session

Method of measurement
Numbers-counting

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Common physiotherapy treatments including hot pack for 20 minutes, TENS for 20 minutes, Ultrasound therapy for 5 minutes, isometric and isotonic neck exercises 20 times a day each time with 10 seconds of holding position and shoulder girdle isotonic exercises 60 times a day with 10 seconds of holding position. These treatments will be followed by 20 minutes of traction by the “Over-the-door home traction unit”.

Category

Rehabilitation

2

Description

Second intervention group: Common physiotherapy treatments including hot pack for 20 minutes, TENS for 20 minutes, Ultrasound therapy for 5 minutes, isometric and isotonic neck exercises 20 times a day each time with 10 seconds of holding position and shoulder girdle isotonic exercises 60 times a day with 10 seconds of holding position. These treatments will be followed by 20 minutes of traction by the “Air neck traction device”

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul Akram Hospital

Full name of responsible person

Dr. Ali Amiri

Street address

Department of Physiotherapy, The Seventh Floor, Seyedol Shohada Building, Hazrat Rasoul Akram Hospital, Niayesh St. Satar Khan Blv.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Naserbakht

Street address

Between the cross-road of Sheykh Fazlolah and Shahid Chamran, Shahid Hemmat Highway

City

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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

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

School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

Batoul Bagheripour

Position

MSc. Student

Other areas of specialty/work

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Person responsible for scientific 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