

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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

##### Name

Mojtaba Kamyab

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 0947

##### Email address

kamyab.m@iums.ac.ir

#### 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 Committee 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

105/1433/93/3

## 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.

**City**

Tehran

**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 Fazlollah and Shahid Chamran, Shahid Hemmat Highway

**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**

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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## Person responsible for updating data

### Contact

**Name of organization / entity**

School of Rehabilitation Sciences, Iran University of  
Medical Sciences

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MSc. Student

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**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*