

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness of acupuncture intervention with pharmacological treatment in improving neck pain and stiffness in patients with cervical spondylosis - clinical trial

#### Protocol summary

##### Study aim

Comparative Effectiveness of Oral Pharmacotherapy vs. Acupuncture Intervention in Patients with Cervical Spondylosis: Evaluation of Symptom Severity and Neck Range of Motion

##### Design

"A phase 3, randomized, open-label, parallel-group, controlled clinical trial conducted on 80 patients."

##### Settings and conduct

treatment Protocols: Group 1 (Pharmacological Therapy): Patients will receive: Oral piroxicam capsules (10 mg): 1 capsule twice daily (NSAID) Oral methocarbamol tablets (500 mg): 3 tablets (1500 mg) three times daily (muscle relaxant) Treatment duration: 10 days Group 2 (Acupuncture Therapy): Patients will undergo 10 acupuncture sessions over 2 weeks (5 sessions per week). Acupuncture points for cervical spondylosis: SI-3, BL-10, BL-11, BL-14, BL-21, BL-60, LI-4 (for lateral neck pain), LI-17 (for central/posterior pain), DU-14, DU-20, SJ-5, GB-20, GB-21, GB-34, GB-39. Adjunctive Therapies (Both Groups): All patients will be instructed in neck range-of-motion and strengthening exercises. Lifestyle modification education (activity adjustments, posture correction) will be provided. Outcome Assessments: Patients will be evaluated at: Baseline (study initiation) Post-intervention (2 weeks) Follow-ups: 6 weeks and 12 weeks after the last intervention

##### Participants/Inclusion and exclusion criteria

Inclusion criteria for the study: Patients with cervical spondylosis and osteoarthritis, aged 50 to 80 years, who have experienced neck pain and stiffness symptoms for more than 6 months, will be enrolled in the study after providing written informed consent.

##### Intervention groups

The first group will receive oral treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants for 10 days. The second group will undergo 10

sessions of acupuncture therapy over a period of two weeks for treatment.

##### Main outcome variables

VAS; NDI; Cervical ROM

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250514065735N1**

Registration date: **2025-05-29, 1404/03/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2025-05-29, 1404/03/08**

Update count: **0**

##### Registration date

2025-05-29, 1404/03/08

##### Registrant information

##### Name

Davoud Gholami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3639 1775

##### Email address

d\_gholamid@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-05-26, 1404/03/05

##### Expected recruitment end date

2025-07-27, 1404/05/05

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the effectiveness of acupuncture intervention with pharmacological treatment in improving neck pain and stiffness in patients with cervical spondylosis - clinical trial

**Public title**  
Comparison of the effectiveness of acupuncture intervention with pharmacological treatment in improving neck pain and stiffness in patients with cervical spondylosis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Signs of Neck Pain and Stiffness Lasting More Than 6 Months  
**Exclusion criteria:**  
Clinical signs of effusion, inflammation, redness Rheumatoid arthritis, Inflammatory arthropathy, Fibromyalgia Collagen vascular disease (Lupus), Gout, Cervical disc pathology Trauma, Fracture, Cervical spine surgery History of allergy and Allergic reaction to medications used (NSAIDs and Methocarbamol)

**Age**  
From **50 years** old to **80 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization in this study will use a permuted block design with a block size of 4. In this method: "A" represents a participant receiving the intervention (acupuncture). "B" represents a participant in the control group (pharmacotherapy). Implementation: All possible 4-sequence permutations (total of 6 combinations) will be used: ABAB BABA AABB BBAA ABBA BAAB Blocks of 4 will be randomly selected to ensure balanced group allocation.

**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

Ethics Committee of Shiraz University of Medical Sciences

##### Street address

Ethics Committee, Office of Research Affairs 3rd Floor, Building No. 3 School of Medicine, Shiraz University of Medical Sciences Imam Hossein Square, Zand Street Shiraz, Iran

##### City

Shiraz

##### Province

Fars

##### Postal code

7134845794

#### Approval date

2025-02-01, 1403/11/13

#### Ethics committee reference number

IR.SUMS.MED.REC.1403.732

## Health conditions studied

### 1

#### Description of health condition studied

Cervical spondylosis without myelopathy or radiculopathy

#### ICD-10 code

M47.812

#### ICD-10 code description

Cervical spondylosis without myelopathy or radiculopathy

## Primary outcomes

### 1

#### Description

VAS (Visual Analog Scale) Assessment Protocol: Pain intensity will be evaluated using the Visual Analog Scale (VAS) at the following time points: Baseline (upon study entry) Post-intervention follow-ups: Week 2 Week 6 Week 12

#### Timepoint

Baseline (upon study entry) Post-intervention follow-ups: Week 2 Week 6 Week 12

#### Method of measurement

VAS (Visual Analog Scale) Assessment Protocol

### 2

#### Description

NDI (Neck Disability Index) Assessment Protocol: The Neck Disability Index (NDI) questionnaire will be used to

evaluate the severity of pain-related disability at the following intervals: Baseline (pre-intervention)Post-treatment follow-ups: Week 2Week 6Week 12

#### **Timepoint**

Baseline (pre-intervention)Post-treatment follow-ups: Week 2Week 6Week 12

#### **Method of measurement**

NDI (Neck Disability Index) Assessment Protocol

## **Secondary outcomes**

### **1**

#### **Description**

Cervical Spine Range of Motion (ROM) Assessment Protocol Measurement Method: Cervical ROM will be quantitatively evaluated using a goniometer at the following time points: Baseline (pre-intervention)Post-intervention follow-ups: Week 2Week 6Week 12

#### **Timepoint**

Baseline (pre-intervention)Post-intervention follow-ups: Week 2Week 6Week 12

#### **Method of measurement**

goniometer

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Pharmacological Treatment Protocol: Piroxicam (NSAID):Dosage: 10 mg oral capsule Frequency: 1 capsule twice daily (BID)Duration: 10 days Methocarbamol (Muscle Relaxant):Dosage: 500 mg oral tablet Frequency: 3 tablets (1500 mg) three times daily (TID)Duration: 10 days

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Intervention group: Acupuncture Points for Cervical Spondylosis: Standard Points:SI-3 (Houxi)BL-10 (Tianzhu)BL-11 (Dazhu)BL-14 (Jueyinshu)BL-21 (Weishu)BL-60 (Kunlun)LI-4 (Hegu) – For lateral neck painLI-17 (Tianding) – For central/posterior painDU-14 (Dazhui)DU-20 (Baihui)SJ-5 (Waiguan)GB-20 (Fengchi)GB-21 (Jianjing)GB-34 (Yanglingquan)GB-39 (Xuanzhong)Clinical Rationale: Local Points (e.g., GB-20, BL-10): Target neck stiffness/pain directly. Distal Points (e.g., LI-4, GB-34): Enhance systemic analgesia and Qi flow.DU/GV Points (e.g., DU-14): Regulate Governor Vessel for spinal support.

#### **Category**

Treatment - Devices

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Emtyaz Hospital

##### **Full name of responsible person**

Davoud Gholami

##### **Street address**

First Alley, First Nayesh Street Nayesh Boulevard Abivardi District

##### **City**

shiraz

##### **Province**

Fars

##### **Postal code**

۷۱۹۴۸۱۵۷۱۱

##### **Phone**

+98 71 3636 4001

##### **Email**

rajaeehospital@sums.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Vice Chancellor for Research and Technology

##### **Street address**

7th Floor, Main Administration Building Shiraz University of Medical Sciences Zand Street

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

7134814336

##### **Phone**

+98 71 3212 2430

##### **Email**

vcrdep@sums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Shiraz University of Medical 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Davoud Gholami

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

No. 366, Street 8, Nastran 2 Ave, Goldasht maali abad

**City**

Shiraz

**Province**

Fars

**Postal code**

7188667917

**Phone**

+98 71 3639 1775

**Fax****Email**

d\_gholamid@sums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Davoud Gholami

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

No. 366, Street 8, Nastran 2 Ave, Goldasht maali abad

**City**

Shiraz

**Province**

Fars

**Postal code**

7188667917

**Phone**

+98 71 3639 1775

**Fax****Email**

d\_gholamid@sums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Davoud Gholami

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

No. 366, Street 8, Nastran 2 Ave, Goldasht maali abad

**City**

Shiraz

**Province**

Fars

**Postal code**

7188667917

**Phone**

+98 71 3639 1775

**Fax****Email**

d\_gholamid@sums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available