

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The comparison of the effects of two compounded treatment on pain and functional improvement in patients with lumbar disc herniation

#### Protocol summary

##### Summary

Objective: The comparison of the effects of two compounded treatments-traction and stabilization exercises versus manipulation and stabilization exercises-on pain and functional improvement in patients with lumbar disc herniation. Design: containing 40 patients with sub-acute or chronic lumbar disc herniation that referred to Shiraz University of medical science physical therapy clinics that randomized by "research randomizer" program into 2 practical groups with 20 participants in each group, single blinded, parallel. Setting and conduct: including 5 visits of manipulation in first group and 5 visits of traction in second group, then 12 visits of core stabilization exercises in both groups. Participants: Inclusion criteria includes: sub-acute or chronic phase of lumbar disc herniation; disc herniation in L4-L5 or L5-S1 levels unilaterally, Exclusion criteria includes: surgery of lumbar region; degenerative joint diseases in lumbar region. Intervention: The first group patients treated with high-velocity low-amplitude spinal manipulation to the sacroiliac joint and lumbar spine for five sessions through ten days and The second group patients treated with motorized lumbar traction for five sessions through ten days, then both group treated by twelve sessions of unsupervised core stability exercise through six week (two sessions per week) in the same situations. Main outcome measures: outcomes were assessed using visual analogue scale for lumbar and leg pain separately and Oswestry Disability Questionnaire for functional disability at baseline, after 5 sessions of treatment (manipulation or traction) and after finishing of core stabilization exercise period.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201406249440N7**

Registration date: **2015-08-05, 1394/05/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-08-05, 1394/05/14

##### Registrant information

###### Name

Soraya Pirouzi

###### Name of organization / entity

School of Rehabilitation Sciences, Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1626 5108

###### Email address

piroozis@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

##### Expected recruitment start date

2013-12-10, 1392/09/19

##### Expected recruitment end date

2015-04-15, 1394/01/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of the effects of two compounded treatment on pain and functional improvement in

patients with lumbar disc herniation

## Public title

The comparison of the effects of two physiotherapy compounded treatments on improvement of lumbar disc herniation symptoms

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria for both group: sub-acute or chronic phase of lumbar disc herniation; disc herniation in L4-L5 or L5-S1 levels unilaterally and by CT-Scan or M.R.I confirmed; symptoms period between 1-12 month(s); leg pain domination versus lumbar pain; pain-free barrier in manipulation. Exclusion criteria for both groups: sequestration of herniated disc; surgery of lumbar region; degenerative joint diseases in lumbar region; progressive neurological symptoms; sphincter dysfunction; cauda equina syndrome; lumbar Spondylolisthesis; spinal canal stenosis; spinal tumors

## Age

From **20 years** old to **50 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

participants randomized by "research randomizer" program into 2 practical groups

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic committee of Vice chancellor for research and Technology, Shiraz University of Medical Science

##### Street address

Shiraz University of Medical Sciences, Zand St.

##### City

Shiraz

##### Postal code

7194733669

## Approval date

2013-08-10, 1392/05/19

## Ethics committee reference number

CT-92-6927

## Health conditions studied

### 1

#### Description of health condition studied

M51.1

#### ICD-10 code

Lumbar and

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

lumbar pain

#### Timepoint

before intervention, after 5 sessions of manipulation or traction, after intervention

#### Method of measurement

visual analog scale (100 degree)

### 2

#### Description

leg radicular pain

#### Timepoint

before intervention, after 5 sessions of manipulation or traction, after intervention

#### Method of measurement

visual analog scale (100 degree)

### 3

#### Description

disability

#### Timepoint

before intervention, after 5 sessions of manipulation or traction, after intervention

#### Method of measurement

Oswestry Disability Questionnaire (ODQ)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

first group intervention: high-velocity low-amplitude spinal manipulation to the sacro-iliac joint and lumbar spine for five sessions through ten days, then twelve sessions of unsupervised core stability exercise through six weeks

#### Category

Rehabilitation

## 2

### Description

second group intervention: motorized lumbar traction for five sessions through ten days, then twelve sessions of unsupervised core stability exercise through six weeks

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr Soraya Pirouzi

##### Street address

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research and technology, Shiraz University of Medical Sciences

##### Full name of responsible person

Dr Poostforoosh

##### Street address

Chancellery of Research and Technology, Level 7, Shiraz University of Medical Sciences, Zand Ave

##### City

Shiraz

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice chancellor for research and technology, Shiraz 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, Shiraz University of Medical Sciences

#### Full name of responsible person

Dr. Soraya Pirouzi

#### Position

Professor Assistance

#### Other areas of specialty/work

#### Street address

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### Contact

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Professor assistant

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## Person responsible for updating data

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School of Rehabilitation Sciences, Shiraz University of Medical Sciences

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Dr Soraya Pirouzi

#### Position

Professor Assistance

#### Other areas of specialty/work

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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*