# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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)

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**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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*