

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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+98 71 1626 5108

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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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Full name of responsible person

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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