Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 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

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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

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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