

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 May 2019

Spinal manipulation in the treatment of patients with MRI-confirmed lumbar disc herniation who had sacroiliac joint hypomobility: a quasi-experimental study

Protocol summary

Summary

Objective: To investigate the effect of lumbar and sacroiliac joint (SIJ) manipulation on pain and functional disability in patients with lumbar disc herniation (LDH) concomitant with SIJ hypomobility. Methods: Twenty subjects with LDH suffering from SIJ hypomobility will receive five sessions of spinal manipulative therapy (SMT) to the SIJ and lumbar spine through two weeks. Back and leg pain intensity and functional disability level will be assessed by Numerical Rating Scale (NRS) and Oswestry Disability Index (ODI), at baseline, immediately after, 3rd and 5th session and one month after the treatment. Inclusion criteria: Age between 20 and 50 years old; MRI-proven unilateral lumbar disc herniation; Symptomatic lumbar disc disease at one segment (L4-L5 or L5-S1); Ipsilateral sacroiliac joint hypomobility; Leg pain during one to 10 months before the study; Leg pain over previous 24 hours should be 30-70 out of 100. Exclusion criteria: Sequestered lumbar disc herniation; Spinal canal stenosis; Spondylololsthesis; Previous lumbar surgery; Gross instability; Positive SLR test

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011924149N33**
 Registration date: **2017-02-19, 1395/12/01**
 Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-19, 1395/12/01

Registrant information

Name

Fahimeh Kamali

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2010-01-21, 1388/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Spinal manipulation in the treatment of patients with MRI-confirmed lumbar disc herniation who had sacroiliac joint hypomobility: a quasi-experimental study

Public title

Spinal manipulation in the treatment of patients with lumbar disc herniation who had sacroiliac joint hypomobility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 20 and 50 years old; MRI-proven unilateral lumbar disc herniation; Symptomatic lumbar disc disease at one segment (L4-L5 or L5-S1); Ipsilateral sacroiliac joint hypomobility; Leg pain during one to 10 months before the study; Leg pain over previous 24 hours should be 30-70 out of 100. Exclusion criteria: Sequestered lumbar disc herniation; Spinal canal stenosis; Spondylololsthesis; Previous lumbar surgery; Gross instability; Positive SLR test

Age

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

Gender

Both

Phase
2-3

Groups that have been masked
None

Sample size
Target sample size: 20

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Vice-Chancellery for Research Office, Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Blvd, Shiraz

City

Shiraz

Country

Iran (Islamic Republic of)

Postal code

Approval date

2009-08-03, 1388/05/12

Ethics committee reference number

CT-88-4614

Health conditions studied

1

Description of health condition studied

lumbar disc herniation

ICD-10 code

M51.2

ICD-10 code description

Other specified intervertebral disc displacement

Primary outcomes

1

Description

Pain intensity

Timepoint

Before, Immediately, 3rd session, 5th session and a

month after intervention

Method of measurement

VAS

2

Description

Disability level

Timepoint

Before, 3rd session, 5th session and a month after intervention

Method of measurement

Oswestry pain and disability questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: five sessions of lumbar rotational and sacroiliac joint manipulation, every other day

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation Sciences, Shiraz University of Medical Sciences

Full name of responsible person

Esmail Shokri

Street address

Abiverdi St., Chamran Blvd.

City

Shiraz

Country

Iran (Islamic Republic of)

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellery for Research Affairs, Shiraz University of Medical Sciences

Full name of responsible person

Basir Hashemi

Street address

Central Building of Shiraz University of Medical Sciences, Zand Blvd., Shiraz

City

Shiraz

Country

Iran (Islamic Republic of)

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Vice Chancellery for Research Affairs, 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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Other areas of specialty/work
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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