Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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: Sequestrated lumbar disc herniation; Spinal canal stenosis; Spondylolysthesis; 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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+98 71 1627 1551

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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: Sequestrated lumbar disc herniation; Spinal canal stenosis; Spondylolysthesis; 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
No information

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

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
Esmaeil Shokri

Street address
Abiverdi St.و Chamran Blvd.

City
Shiraz

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

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

School of Rehabilitation Sciences, Shiraz University of Medical Sciences

Full name of responsible person

Fahimeh Kamali

Position

Associate Professor

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