

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1627 1551

###### Email address

kamalif@sums.ac.ir

##### 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**  
 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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## Person responsible for scientific inquiries

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 Associate Professor

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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
 School of Rehabilitation Sciences, Shiraz University of Medical Sciences  
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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