

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Effect of Manual Therapy on Pain and Disability of Patients with Imaging Proven Herniated Lumbar Disc and Concomitant Sacroiliac Joint Dysfunction

#### Protocol summary

##### Summary

Objectives: the aim of our study is to evaluate effect of manual therapy on pain and disability of patients with imaging proven herniated lumbar disc and concomitant sacroiliac joint dysfunction. Methods: following randomized selection of 47 subjects, more than or equal to 18 years with image proven herniated lumbar disc and physical findings of concomitant SIJD (Sacroiliac Joint Dysfunction), routine physical or manual therapy would be applied to two separated groups. For all of patients, electrodiagnostic evaluation prior to beginning of therapy, and VAS, Margolis pain drawing and Oswestry functional disability scoring at three times, before starting of 1st (baseline), 3rd and 6th therapy sessions will done. The data were statistically analyzed using t-test and ANOVA statistical methods. SPSS 11.5 software will be used for statistical analysis of findings.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014110719839N1**

Registration date: **2016-02-23, 1394/12/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-02-23, 1394/12/04

##### Registrant information

##### Name

Seyed Pezhman Madani

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8896 9331

##### Email address

madani.p@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2010-12-31, 1389/10/10

##### Expected recruitment end date

2013-12-31, 1392/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Manual Therapy on Pain and Disability of Patients with Imaging Proven Herniated Lumbar Disc and Concomitant Sacroiliac Joint Dysfunction

##### Public title

Effect of Manual Therapy on Pain and Disability of Patients with Imaging Proven Herniated Lumbar Disc and Concomitant Sacroiliac Joint Dysfunction

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

We include the subjects with age  $\geq 18$  years old; both male and female provided paracentral or intraforaminal herniated lumbar discs on magnetic resonance imaging (MRI) and physical exam results indicative of lumbosacral root irritation concomitant with SIJ dysfunction. Patients with positive history of lumbar spine surgery, spinal or

hip fractures, osteoporosis, severe hip joint degenerative disorders, diabetes mellitus and polyneuropathy, progressive neurological deficit signs owing to discopathy, relative contraindication for electrodiagnostic exam or manual therapy also all of subjects had current pregnancy or unfinished extensive physical examination for any reason, would be excluded.

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **47**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Hemmat highway

**City**

Tehran

**Postal code****Approval date**

2001-08-20, 1380/05/29

**Ethics committee reference number**

496

**Health conditions studied****1****Description of health condition studied**

Sacroiliac joint dysfunction

**ICD-10 code**

M 54.5

**ICD-10 code description**

Low back pain

**Primary outcomes****1****Description**

Pain

**Timepoint**

At the beginning and 6th session

**Method of measurement**

VAS

**Secondary outcomes****1****Description**

disability

**Timepoint**

at the beginning and 6 wks

**Method of measurement**

oswestry questionnaire

**2****Description**

Pain area

**Timepoint**

At the beginning and 6th session

**Method of measurement**

Margolis

**Intervention groups****1****Description**

Manual therapy techniques in case group

**Category**

Rehabilitation

**2****Description**

Routin physical thera y modalities such as heat and electrotherapy in control group

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shafa Yahyaian Rehabilitation Hospital

**Full name of responsible person**

Seyyed Pezhman Madani

**Street address****City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mrs. Kordloo

**Street address**

Research Office, Iran University of Medical Sciences,  
Hemmat highway

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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

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Iran University of Medical Sciences

**Full name of responsible person**

Seyed Pezhman Madani

**Position**

Assistant professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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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*