

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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)

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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 ≥ 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

Name of organization / entity

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Full name of responsible person

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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