Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Country

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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 beggining 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 theray 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

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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

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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