

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Spinal Manipulation and Muscle Energy Technique on Pain, Function, Thickness of muscles for Patients with Sacroiliac Joint Dysfunction

Protocol summary

Study aim

The purpose of study is to examine the effect of spinal manipulation therapy and muscle energy technique on pain, function and thickness(at rest, contracted and percent change thickness of the deep abdominals(Internal oblique ,Transverse abdominal) Global muscles Latissimus dorsi and Gluteus maximus)

Design

In this research, 44 eligible patients of Sacroiliac Joint Dysfunction referring to Life Line Hospital, Gulab daivi hospital and Ganj Baksh Spinal Research Hospital were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into Four Groups.(Three Intervention Groups and One Control Group)

Settings and conduct

After approval of proposal from institutional review committee a randomized clinical trial study of 7 months duration will be conducted at Ganj Baksh spinal research and rehabilitation hospital-trust, Life Line hospital and Gulab devi hospital ,department of Physical therapy ferozpur road Lahore Pakistan. Baseline pre-treatment measurements will be compared with post-treatment measurement that will be taken after one month and three months follow up interval. It is double blinded study, assessor and patients will be blinded by following procedure. Assessors will be blinded by assigning specific identity numbers and all consent, readings forms will be placed in locker to bind assessors (Arif, Raham) and to ensure data safety.. Patients will be blinded from group treatments and hypothesis by informing partial information regarding treatment groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male patients between 18 to 45 years old with unilateral low back pain up to knee will be included. At least three out of six sacroiliac joint provocation tests with standing flexion test and seating

flexion test must be positive. No strengthening exercise of muscles in last three months. No surgical history. No disc pathology confirmed by MRI. No facet joint hypo mobility. No ankylosing spondylitis. Exclusion criteria: Abnormal recording of thickness by ultrasound. fatigability of subjects Over time Unwillingness of subjects to continue testing due to fear.

Intervention groups

There are four groups ,Three Experimental Groups and one Control Group respectively , 1. Muscle Energy Group, 2. Spinal Manipulation Therapy group, 3. Muscle Energy with Spinal Manipulation Therapy Group. 4.Control Group(Conventional Group) Treatment session for each group will be twice a week for four weeks.

Main outcome variables

Outcomes will be measured using modified Oswestry disability index score for function, numeric pain rating scale for pain and ultrasonography for muscle thickness.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090301001722N16**

Registration date: **2018-02-08, 1396/11/19**

Registration timing: **retrospective**

Last update: **2018-02-08, 1396/11/19**

Update count: **0**

Registration date

2018-02-08, 1396/11/19

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences-International Campus

Expected recruitment start date

2017-04-01, 1396/01/12

Expected recruitment end date

2017-10-31, 1396/08/09

Actual recruitment start date

2017-04-01, 1396/01/12

Actual recruitment end date

2017-10-31, 1396/08/09

Trial completion date

empty

Scientific title

Effects of Spinal Manipulation and Muscle Energy Technique on Pain, Function, Thickness of muscles for Patients with Sacroiliac Joint Dysfunction

Public title

Effects of Spinal Manipulation and Muscle Energy Technique on Sacroiliac Joint Dysfunction.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: 18-45years old with unilateral LBP upto knee At least three out of six SIJ provocation tests must be positive. Standing flexion test and seating flexion test must be positive. Male No strengthening exercise of muscles in last three months. No surgical history No disc pathology confirmed by MRI No facet joint hypomobility No ankylosing spondylitis

Exclusion criteria:

Abnormal recording of thickness by ultrasound. Over time and fatigability of subjects. Unwillingness of subjects to continue testing

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Four groups will be divided by simple random sampling

by using Four alphabetic chance: A) First group, B) second group and C) third group. D) Fourth Group Patients will be assigned randomly in Four groups by Physical Therapist (Rabiya) by using concealed opaque envelope mentioning Specific Identity Numbers generated through Random Number Generator to avoid biasness.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double Blind: Assessor Blind: Data safety will be ensured by assigning Specific Identity numbers and all consent, readings forms will be placed in locker to bind Assessors (Arif, Amir). Patients Blind: Patients will be blinded from group treatments and Hypothesis by informing partial information regarding treatment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tehran University of Medical Sciences

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Keshavarz Blvd. Kods street ,Tehran Tehran Tehran Iran, Islamic Republic Of 14167

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Province

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Postal code

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Approval date

2017-10-09, 1396/07/17

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3668

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

Sacroiliac Joint Dysfunction

ICD-10 code

M99.04

ICD-10 code description

Diseases of the musculoskeletal system and connective tissue, Biomechanical lesions, not elsewhere classified, Segmental and somatic dysfunction, Sacral region

Primary outcomes

1

Description

Pain

Timepoint

Before Intervention,After One month,After three months follow up

Method of measurement

Numeric Pain Rating Scale

2

Description

Muscle Thickness (Rest,Contracted,Percent change)

Timepoint

Muscle Thickness(at rest,contracted and Percent change) will be measured before treatment ,after treatment at one month and follow up three months

Method of measurement

Ultrasonography

Secondary outcomes

1

Description

Function

Timepoint

Function will be measured before treatment , after treatment at one month and follow up three months

Method of measurement

Modified Oswestry Disability Index Score.

Intervention groups

1

Description

Intervention group: Muscle Energy Technique. Treatment session will be twice a week for four weeks.

Category

Rehabilitation

2

Description

Intervention group: Spinal Manipulation Therapy. Treatment session will be twice a week for four weeks.

Category

Rehabilitation

3

Description

Intervention group: Muscle Energy with Spinal Manipulation Therapy. Treatment session will be twice a week for four weeks.

Category

Rehabilitation

4

Description

Control group: Conventional Therapy such as,Therapeutic Ultrasound. Treatment session will be twice a week for four weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Life Line Hospital,

Full name of responsible person

Dr.Mohammad-Reza Hadian Rasanani

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Recruitment center

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Sponsors / Funding sources

1

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Full name of responsible person

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available