Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Name

Samira Karimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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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
Street address
Keshavarz Blvd. Kods street ,Tehran Tehran Tehran Iran, Islamic Republic Of 14167
City
Tehran
Province
Tehran
Postal code
14167
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
Street address
Johar Town,near khokhar chowk ,Lahore. Life Line Hospital, Punjab Pakistan 54000
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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

Name of organization / entity

Rehabilitation Faculty,Department of Physiotherapy

Full name of responsible person

Dr.Mohammad-Reza Hadian Rasanani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Mohammad-Reza Hadian Rasanani

Position

Professor

Latest degree

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Other areas of specialty/work

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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