

Clinical Trial Protocol

Iranian Registry of Clinical Trials

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COMPARATIVE ANALYSIS ON THE EFFECTIVENESS OF MUSCLE ENERGY TECHNIQUE AND MAITLAND MOBILIZATIONS IN THE MANAGEMENT OF CHRONIC SACRO ILIAC JOINT DYSFUNCTION FOR IMPROVING PAIN AND DISABILITY: A RANDOMIZED CONTROL TRIAL

Protocol summary

Study aim

To compare the effectiveness of Muscle Energy Technique with Maitland Mobilizations in patients with chronic Sacroiliac Joint Dysfunction in reducing pain and disability.

Design

A single blind Randomized controlled trial with a parallel group design of 60 patients had random allocation by Chit-Box method.

Settings and conduct

Patients from the Physical-Therapy departments of Khyber Teaching Hospital, Lady Reading Hospital, Peshawar Pakistan. The outcome assessor had been kept blind during the trial.

Participants/Inclusion and exclusion criteria

Inclusion Criteria □ Age group between 25- 55 years □ Both Male and Female patients □ Chronic cases of SIJ dysfunction □ Patients with at least moderate score (21%-40%) in MODI □ Patients with 3 or 4 positive SIJ provocative test Exclusion Criteria □ Patients with LBP or acute discogenic sciatic pain. □ Patients who are previously on injections into SI joint. □ Piriformis syndrome. □ Hip joint pathology □ Trochanter pain syndrome □ Facet joint arthropathy □ Rheumatoid arthritis □ Ankylosing spondylitis □ Radiculopathy □ Visceral referral pain □ Stress fracture □ Malignancy □ Patients with any Co-morbid condition.

Intervention groups

The patients were recruited in two groups i.e. group A and group B by Randomization through Chit-box method. Group-A (Experimental Group) patients had been treated with MET and Lumbopelvic Stability Exercises and Group-B (Control Group) patients had been treated with Maitland Mobilizations and Lumbopelvic Stability Exercises. The patients in both the groups had received a series of twelve treatment sessions and a follow up

consultation over a maximum period of four weeks. The readings were taken for two times during the whole session.

Main outcome variables

□ VAS (Visual Analogue Scale) for measuring the Pain. □ MODI (Modified Oswestry Disability Index) for measuring the Disability.

General information

Reason for update

Acronym

SIJD

IRCT registration information

IRCT registration number: **IRCT20190618043930N1**

Registration date: **2019-07-14, 1398/04/23**

Registration timing: **prospective**

Last update: **2019-07-14, 1398/04/23**

Update count: **0**

Registration date

2019-07-14, 1398/04/23

Registrant information

Name

Faryal Zaidi

Name of organization / entity

The University of Lahore

Country

Pakistan

Phone

+92 42 37592112

Email address

faryal.pt@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2635-09-06, 2014/06/15

Expected recruitment end date

2635-10-22, 2014/07/30

Actual recruitment start date

2635-12-22, 2014/10/01

Actual recruitment end date

2636-03-04, 2014/12/14

Trial completion date

2636-07-21, 2015/04/30

Scientific title

COMPARATIVE ANALYSIS ON THE EFFECTIVENESS OF MUSCLE ENERGY TECHNIQUE AND MAITLAND MOBILIZATIONS IN THE MANAGEMENT OF CHRONIC SACRO ILIAC JOINT DYSFUNCTION FOR IMPROVING PAIN AND DISABILITY: A RANDOMIZED CONTROL TRIAL

Public title

MUSCLE ENERGY TECHNIQUE AND MAITLAND MOBILIZATIONS IN TREATING CHRONIC SACRO ILIAC JOINT DYSFUNCTION

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic cases of Sacro Iliac Joint dysfunction Patients with at least moderate score (21%-40%) in Modified Oswestry Disability Index Patients with 3 or 4 positive Sacro Iliac Joint provocative test

Exclusion criteria:

Patients with Low Back Pain or acute discogenic sciatic pain. Patients who are previously on injections into SI joint Piriformis syndrome. Hip joint pathology Trochanter pain syndrome Facet joint arthropathy Rheumatoid arthritis Ankylosing spondylitis Radiculopathy Visceral referral pain Stress fracture Malignancy Patients with any Co-morbid condition.

AgeFrom **25 years** old to **55 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **60**Actual sample size reached: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

The patients were recruited in two groups i.e. group A and group B by Randomization through Chit-box method. Group-A (Experimental Group) patients had been treated with MET and Lumbopelvic Stability Exercises and Group-B (Control Group) patients had been treated with Maitland Mobilizations and Lumbopelvic Stability Exercises. Chit-Box Method: For random allocation of 60 cases into two groups equally, prepare 60 chits writing

“C” (for Control group) on 30 chits and “E” (for Experimental group) on 30 chits. After folding the chits and putting in a box and well mixing, draw a chit, note the letter written on it, and then draw the second chit without replacing the first, note it and proceed similarly until the last i.e. 60th chit is drawn. The generated random allocation sequence may be one as appears in Table below . According to this sequence the first case registered will go to the control group, second case again to the control group, the third to the experimental group and so on to the last case to control group. Draw 1st 2nd 3rd -- 15th Result (Letters on chit) C C E C E C C E C C E E -- E C E C Registered Case No. (No. Allocation) 1 2 3 4 5 6 7 8 9 10 11 12 -- 57 58 59 60

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome Assessor has been kept blind during the trial

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Advanced Studies & Research Board of Khyber Medical University

Street address

Block-IV PDA building, Phase-V Hayatabad

City

Peshawar

Postal code

25000

Approval date

2014-09-29, 1393/07/07

Ethics committee reference number

ASRB000223/CA/IPM&R

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

The “Sacroiliac Joint (SIJ) Dysfunction” indicates a pain in the SI joint region that is usually caused by either too much movement (hypermobility) or too little movement (hypo mobility) at the joint that typically results in an irritation of the joint. The mechanical SIJ dysfunction typically causes a dull ache that is located at the base of the spine on the affected side. The pain may become worse and 'sharp' in nature during the activities such as sitting, bending, lifting, standing up from a seated position, or lifting the knee up to the chest during stair

climbing. Sometimes the pain can refer to the groin, buttock or the back of the thigh but rarely goes below the knee. The patients with severe and disabling SI joint dysfunction can suffer from insomnia and depression. The main causes of SIJ dysfunction are hypermobility i.e. ligamentous laxity and hypomobility i.e. degenerative joint disease, traumatic incident, hormonal imbalance, unilateral weak lower limb, reversal of concavo-convex locking relationship of SI joint, scoliosis, lumbar spinal fusion, spondyloarthropathies, hip osteoarthritis, femoroacetabular impingement, leg-length inequality, poor-quality footwear, biomechanical or muscle length imbalances.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

PAIN

Timepoint

At the start of intervention and then after one month (12 sessions) of treatment administration

Method of measurement

VAS (Visual Analogue Scale) for measuring the Pain.

Secondary outcomes

1

Description

DISABILITY

Timepoint

At the start of intervention and then after one month (12 sessions) of treatment administration.

Method of measurement

MODI (Modified Oswestry Disability Index) for measuring the Disability

Intervention groups

1

Description

Intervention group: Group-A of 30 patients (Experimental group) was treated with Muscle Energy Technique that was applied on Quadratus Lumborum, Iliopsoas and Piriformis muscles of the affected side for 1 set of 5 repetitions with 10 sec hold along with Lumbopelvic stability exercises which were targeted to the ipsilateral gluteus maximus, contralateral latissimus dorsi and abdominals in 3 sets of 10 reps with 10 sec hold.

Category

Treatment - Other

2

Description

Control group: Group-B of 30 patients (Control group) was treated with Sacroiliac Joint Maitland mobilizations in

3 sets of 30 oscillations each on the affected side along with Lumbopelvic stability exercises which were targeted to the ipsilateral gluteus maximus, contralateral latissimus dorsi and abdominals in 3 sets of 10 reps with 10 sec hold.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khyber Teaching Hospital

Full name of responsible person

Dr. Abid Ali

Street address

University Rd, Rahat Abad

City

Peshawar

Postal code

25000

Phone

+92 922 440008

Fax

+92 91 9224423

Email

info@kth.com.pk

Web page address

<https://www.kth.gov.pk/>

2

Recruitment center

Name of recruitment center

Lady Reading Hospital

Full name of responsible person

Dr. Muhammad Khan

Street address

Hospital Road

City

Peshawar

Postal code

25000

Phone

+92 91 9211441

Fax

+92 91 9211401

Email

info@lrh.gov.pk

Web page address

<https://lrh.edu.pk/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

khyber medical university

Full name of responsible person

Dr. Mohammad Bin Afser Jan

Street address

Block-IV, PDA building, Phase-V Hayatabad

City

Peshawar

Postal code

25000

Phone

+92 91 5892885

Email

ipmr@kmu.edu.pk

Web page address

<http://www.kmu.edu.pk/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

khyber medical university

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

The University of Lahore

Full name of responsible person

Faryal Zaidi

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Japan Road Sihala

City

Islamabad

Province

Punjab

Postal code

75500

Phone

+92 42 111 865 865

Email

faryal.pt@gmail.com

Web page address

<https://www.uol.edu.pk/campuses/islamabadcampus>

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Lahore

Full name of responsible person

Faryal Zaidi

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Japan Road, Sihala

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75500

Phone

+92 42 37592112

Fax

Email

faryal.pt@gmail.com

Web page address

<https://www.uol.edu.pk/campuses/islamabadcampus>

Person responsible for updating data

Contact

Name of organization / entity

The University of Lahore

Full name of responsible person

Faryal Zaidi

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Japan Road, Sihala

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Province

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Postal code

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+92 42 37592112

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faryal.pt@gmail.com

Web page address

<https://www.uol.edu.pk/campuses/islamabadcampus>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Informed Consent Form, Clinical Study Report, Analytic

Code files could be shared

When the data will become available and for how long
2 months after publication

To whom data/document is available
people working in academic institutions or people working in businesses can also apply to receive it

Under which criteria data/document could be used
Intervention purpose

From where data/document is obtainable
Faryal.pt@gmail.com

What processes are involved for a request to access data/document
Full description about the Purpose/Aim of using the documents
Insight about the Disorder and intervention of the research

Comments