Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Impact of Muscle Energy Technique combined with dry needling VS Muscle Energy Technique combined with electro-acupuncture on pain, pelvic realignment, performance, muscle thickness, and stiffness for managing patients with anterior innominate iliosacral dysfunction.

Protocol summary

Study aim

Approach treat anterior innominate rotation iliosacral

Design

Each group received a total of 6 sessions (3 per week) for two weeks. Participants were informed about the study's purpose and treatment frequency but were not made aware of the specific therapy method. Informed consent was obtained, and participants were scheduled on different days to minimize evaluator bias. Baseline and post-treatment evaluations were conducted by a separate physiotherapist.

Settings and conduct

The study used a simple randomization method and a double-blind design, with participants blinded to group assignments. Data was collected from demographic data and evaluated at baseline and after six treatment sessions, including pain intensity, pelvic alignment, muscle thickness, and functional performance.

Participants/Inclusion and exclusion criteria

The study of chronic low back pain (LBP) in individuals aged18-50 with a BMI of 18.5-30 kg/m², a VAS score of 3-8, and a diagnosis of chronic SIJ syndrome aims to Participants must have stable physical activity and have not had dry needling or electro-acupuncture in the last 6 months. Exclusion criteria include contraindications, significant musculoskeletal conditions, neurological disorders, severe comorbidities, pregnancy, pelvic surgery history, medications, allergies, psychiatric disorders, substance use, and recent trauma.

Intervention groups

Group A: Muscle energy Technique with Sham dry needling (MET + SDN) Group B: Muscle energy Technique with dry needling (MET + DN) Group C: Muscle energy Technique with electroacupuncture (MET + EA) Group D: Muscle energy Technique with Sham electroacupuncture (MET + SEA)

Main outcome variables

The study used various primary outcome measures, including visual analogue scale, photogrammetry, SF-36, lumbar spine range of motion, ASLR test, pain threshold pressure algometry, and sonographic assessment.

General information

Reason for update

Acronym

AIISJD

IRCT registration information

IRCT registration number: **IRCT20250610066158N1**
Registration date: **2025-07-16, 1404/04/25**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-16, 1404/04/25**
Update count: **0**

Registration date

2025-07-16, 1404/04/25

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-01, 1404/02/11

Expected recruitment end date

2025-09-01, 1404/06/10

Actual recruitment start date

2025-05-01, 1404/02/11

Actual recruitment end date

2025-08-01, 1404/05/10

Trial completion date

2025-09-01, 1404/06/10

Scientific title

Impact of Muscle Energy Technique combined with dry needling VS Muscle Energy Technique combined with electro-acupuncture on pain, pelvic realignment, performance, muscle thickness, and stiffness for managing patients with anterior innominate iliosacral dysfunction.

Public title

Impact of Muscle Energy Technique combined with dry needling VS Muscle Energy Technique combined with electro-acupuncture on pain, pelvic realignment, performance, muscle thickness, and stiffness for managing patients with anterior innominate iliosacral dysfunction.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age: 18–50 years BMI of 18.5–30 kg/m² Chronic low back pain (LBP) duration: Minimum of 6 weeks to over 3 months. mechanical and uncomplicated in nature. Pain intensity: VAS score between 3 and 8, indicating moderate to severe pain. Diagnosed chronic SIJ syndrome with at least 3 out of 5 positive SIJ provocation tests Stable physical activity level: Sedentary to moderately active based on IPAQ guidelines. Written informed consent provided, understanding procedures objectives. No dry needling or electro-acupuncture in the last 6 months to avoid treatment bias. Washout period of 3 days for analgesic medication prior to participation.

Exclusion criteria:

Absolute contraindications to SMT. Significant musculoskeletal conditions Neurological disorders affecting lower extremities .Severe comorbidities . Pregnancy or plans for pregnancy during the study period. History of pelvic surgery in the past year. Use of medications altering pain. muscle function unless stabilized for 3 months. Allergies or adverse reactions to needles or electrical stimulation Psychiatric disorders impairing protocol adherence, substance Recent trauma. Participants actively treated at DUT Chiropractic Day Clinic without a 2-week washout period. Participants engaging in major physical activities or taking NSAIDs during the study

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **128**

Actual sample size reached: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants randomized into four groups: Group A: MET + Sham Dry Needling (SDN) Group B: MET+ Dry Needling (DN) Group C: MET + Electro-acupuncture (EA) Group D: MET + Sham Electro-acupuncture (SEA) Simple randomization using a computer-generated list via an online randomization tool. Allocation concealment ensured by using numbered cards in a ball for assignment. Blinding Double-blinded design: radiology and participants blinded to group assignments. Participants unaware of treatments received by others in different groups. Baseline and post-treatment evaluations conducted by independent, blinded physiotherapists. Statistician blinded during data analysis to eliminate bias.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study employed a double-blinded design to minimize bias and ensure the validity of the results. Specifically, both the radiologists and participants were blinded to the group assignments, preventing their expectations from influencing the outcomes. Participants were also unaware of the treatments received by others in different groups, maintaining the integrity of the blinding process. Baseline and post-treatment evaluations were carried out by independent physiotherapists who were blinded to the group allocations, further reducing assessment bias. Additionally, the statistician responsible for data analysis was blinded, ensuring an objective interpretation of the data. Overall, the blinding procedures included blinding of outcome assessors, participants, and data analysts, which enhances the study's internal validity by mitigating potential biases related to expectations and subjective judgments.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

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Approval date

2025-04-24, 1404/02/04

Ethics committee reference number

IR.TUMS.FNM.REC.1404.067

Health conditions studied

1

Description of health condition studied

Anterior innominate iliosacral dysfunction (AIISD)

ICD-10 code

M25.5

ICD-10 code description

Pain in joint

Primary outcomes

1

Description

Pain threshold pressure

Timepoint

first session and after two weeks

Method of measurement

Pressure algometry is a method used to assess pain threshold by applying controlled pressure to a specific body part using an algometer. The threshold is defined as the minimum pressure at which the subject reports the sensation of pain. This technique quantifies pain sensitivity and can be used to evaluate conditions such as fibromyalgia or chronic pain syndromes.

Secondary outcomes

1

Description

Muscle stiffness

Timepoint

first session and after two weeks

Method of measurement

Measurement of gluteus maximus and Medius stiffness is performed using imaging techniques such as ultrasonography These assessments provide quantitative data regarding the structural integrity and functional characteristics of the gluteal muscles. Stiffness measurements can indicate muscular tension and potential dysfunction

Intervention groups

1

Description

Control group: The group A (control group A) was given muscle energy technique with sham dry needling (MET + SDN). Control group: The group D (control group D) received muscle energy technique with sham electroacupuncture (MET + SEA). MET procedure: Patient in supine position on the edge of the bed.The hip joint will be brought to 90 degrees flexion. • Knee on the shoulder, and the therapist holds the shoulder. • The patient asked to extend (20% of muscle contraction), and the therapist resisted. • The contract will hold for 10 seconds, then relax and flex more. This procedure was done three times [treatment frequency: 3 times per week for 6 sessions]. Sham dry needling (SDN) procedure: A sham needle/introducer was created to allow for an identical-appearing needle and introducer, but without inserting the needle (the needle manufacturer is Tianjin, China, brand name Zhongyan Taihe). Prior to the study, a single needle was removed, and its sharp point was first cut off around 5 mm proximal to the tip [. The shortened needle was blunted for safety and then glued into the introducer with clear glue (cyanoacrylate), so it appeared like a normal dry needle (with the thicker end slightly protruding from the introducer). These sham needles thus had no sharp tip protruding, the needle could not be removed from the introducer, and thus the needle never contacted the skin. The practitioner would hold one of these needles in the same manner they would hold a true dry needle and would place it on the patient’s skin. They would tap it identically, but as the needle was glued in, no needle would penetrate the skin. Subjects would still feel the introducer pressed hard against their skin, however, like a prior sham-controlled study. The practitioner would then proceed to gently manipulate the introducer/needle apparatus on the skin, in the same location, for approximately thirty seconds at each location, which matched our approximate clinical time for performing this procedure with the true method. In between patients, the sham needles were placed in 70% isopropyl alcohol to ensure sterility. We will apply a double-sided medical adhesive tape with a thickness to secure the needle onto it. [“Treatment Frequency: 3 times per week for 6 sessions]. Participants who suffer from iliosacral joint pain were included in this study. consisting of 6 sessions of approximately 45 minutes (three times a week for two weeks for all groups). The participants received muscle energy technique correction treatment; all subjects had a pretest before program three times to obtain an accurate result of the degree of alignment of inclination of the iliosacral joint. Also pain, alignment, and functional activities, and retest after six treatment sessions. To evaluate the pain, personal care during lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling, and in addition, the participants were asked not to take analgesics or nonsteroidal anti-inflammatory drugs (NSAIDs) to avoid the analgesic effects of the drugs throughout the study period. Sham electroacupuncture procedure: We will apply a double-sided medical adhesive tape with a thickness to secure the needle onto it, and the TENS (Transcutaneous

Electrical Nerve Stimulation) device is off. [“Treatment Frequency: 3 times per week for 6 sessions]. Procedure for Using Sham Electroacupuncture Without Skin Penetration Objective: We will utilize sham electroacupuncture points to alleviate iliococcygeal joint pain without skin penetration or electrical stimulation, exclusively through the application of adhesive needles. Required Materials: • Non-invasive acupuncture needles designed for superficial application • Medical adhesive • Measuring tape (cun) for precise localization Acupuncture Points Used: BL23 (Shinshu) Location: 1.5 cun lateral to the lower border of the spinous process of the second lumbar vertebra. BL25 (Dachangshu) Location: 1.5 cun lateral to the lower border of the spinous process of the fourth lumbar vertebra. BL26 (Guanyuanshu) Location: 1.5 cun lateral to the lower border of the spinous process of the fifth lumbar vertebra. BL27 (Xiaochangshu) Location: 1.5 cun lateral to the midline, at the level of the first sacral foramen. BL28 (Pangguangshu) Location: 1.5 cun lateral to the midline, at the level of the second sacral foramen. BL54 (Zhibian) Location: On the buttock, in the depression 3 cun lateral to the sacral hiatus. GB30 (Huantiao) Location: At the junction of the lateral one-third and medial two-thirds of the distance between the prominence of the greater trochanter and the sacral hiatus. GV3 (Yaoyangguan) Location: On the midline, in the depression below the spinous process of the fourth lumbar vertebra. Ashi Points (Tender Points) o Location: Specific tender points around the sacroiliac joint and lower back.

Category

Rehabilitation

2

Description

Intervention group: Group B (intervention group B) received muscle energy technique with dry needling (MET + DN). Intervention group: Group C (intervention group C) received muscle energy technique with electroacupuncture (MET + EA). MET procedure Patient in supine position on the edge of the bed. The hip joint will be brought to 90 degrees flexion. • Knee on the shoulder, and the therapist holds the shoulder. • The patient asked to extend (20% of muscle contraction), and the therapist resisted. • The contract will hold for 10 seconds, then relax and flex more. This procedure was done three times [treatment frequency: 3 times per week for 6 sessions]. Dry Needling Procedure: A perpendicular angle (90°) is generally used for superficial and mid-layer trigger points. - For deeper points, such as those near the iliac crest or deeper layers of the gluteus maximus, an angle of 60–75° may be applied to safely reach the targeted area without affecting adjacent structures. Needle Manipulation to Elicit Twitch Responses: - After insertion, the needle is manipulated using techniques such as pistoning (repeated in-and-out motion). These techniques aim to elicit twitch responses, involuntary contractions of muscle fibers. Achieving this response indicates effective targeting of the trigger point. After eliciting twitch responses, the needle is retained for 20 minutes, depending on patient tolerance. [Treatment Frequency: 3 times per week for 6 sessions]. Electroacupuncture procedure : Is an effective treatment for iliosacral (sacroiliac) joint pain by targeting specific acupuncture points with electrical stimulation to enhance therapeutic effects. Below is standardized acupuncture points commonly used in electroacupuncture for treating iliosacral joint pain, along with a reference supporting their use.Standard Electroacupuncture Points for Iliosacral Joint Pain BL23 (Shinshu)• Location: 1.5 cun lateral to the lower border of the spinous process of the second lumbar vertebra.• Function: Strengthens the kidneys and benefits the lumbar region.BL25 (Dachangshu)• Location: 1.5 cun lateral to the lower border of the spinous process of the fourth lumbar vertebra.• Function: Regulates the intestines and strengthens the lower back.BL26 (Guanyuanshu)• Location: 1.5 cun lateral to the lower border of the spinous process of the fifth lumbar vertebra.• Function: Strengthens the lower back and regulates the lower burner.BL27 (Xiaochangshu)• Location: 1.5 cun lateral to the midline, at the level of the first sacral foramen.• Function: Benefits the lumbar region and sacroiliac joint.BL28 (Pangguangshu)• Location: 1.5 cun lateral to the midline, at the level of the second sacral foramen.• Function: Regulates the bladder and strengthens the lumbar region.BL54 (Zhibian)• Location: On the buttock, in the depression 3 cun lateral to the sacral hiatus.• Function: Benefits the lumbar region and alleviates pain.GB30 (Huantiao)• Location: At the junction of the lateral one-third and medial two-thirds of the distance between the prominence of the greater trochanter and the sacral hiatus.• Function: Benefits the hip joint and alleviates pain.GV3 (Yaoyangguan)• Location: On the midline, in the depression below the spinous process of the fourth lumbar vertebra.• Function: Strengthens the lumbar region and legs.Ashi Points (tender points)• Location: Specific tender points around the sacroiliac joint and lower back.• Function: Directly target areas of pain for relief.• In Chinese medicine, "cun" (□) is a traditional unit of measurement used primarily in acupuncture and traditional Chinese medicine (TCM) to locate acupuncture points on the body. The "cun" is a proportional measure, meaning it is relative to the individual's body, and is often translated as "inch" in English[.• Proportional Measurement: The cun is not a fixed length like an inch or a centimeter. Instead, it varies based on the patient's body, making it a proportional measurement that ensures acupuncture points are located accurately regardless of the person's size.• Determining the Cun: Typically, the width of the patient's thumb at the interphalangeal joint (the joint between the first and second phalanges) is used as one cun. Alternatively, the width of the patient's four fingers held together at the level of the proximal interphalangeal joints (the joints in the middle of the fingers) can be considered approximately three cun.• Locating Acupuncture Points: The cun measurement is essential for finding the precise locations of acupuncture points, which are described in TCM texts in terms of their distance from anatomical landmarks. For instance, an acupuncture point might be described as located "2 cun above the wrist crease."[211]Adjusting Intensity and

Frequency of Electrical Impulses in Electroacupuncture for Iliosacral Joint Pain 1. Intensity Adjustment: milliamperes (mA). Procedure—We start with a low-intensity setting (0.5–1.0 mA) and increase gradually until the patient feels a mild tingling sensation or gentle muscle twitching. - The final intensity is determined by the patient's comfort level and should not induce pain or excessive discomfort. - intensities (1.5–2.5 mA) ensuring safety and tolerability. Frequency Adjustment Hertz (Hz). Application: Low frequency (2–10 Hz) Duration and Session Guidelines Typically, 20 minutes. Adjustments to intensity and frequency are made every 5–10 minutes. [Treatment Frequency: 3 times per week for 6 sessions]. The TENS (Transcutaneous Electrical Nerve Stimulation) device is used for stimulation.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
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Grant name
School of Rehabilitation

Grant code / Reference number
IR.TUMS.FNM.REC.1404.067

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
Foreign

Category of foreign source of funding
UN agencies and international organizations

Country of origin

Type of organization providing the funding
Academic

2

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Grant code / Reference number
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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
Foreign
Category of foreign source of funding
UN agencies and international organizations
Country of origin
Type of organization providing the funding
Academic

3

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Grant name
School of rehabilitation
Grant code / Reference number
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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
Foreign
Category of foreign source of funding
UN agencies and international organizations
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
all collected deidentified IPD, IPD collected for the primary outcome measure only
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
only available for people working in academic institutions
Under which criteria data/document could be used
Data will be shared based on request review and approval by a designated data access committee. Deidentified IPD and supporting documents will be available for approved research analyses, with access provided via secure data sharing platforms, specifying allowed uses and duration.
From where data/document is obtainable
email addresses: shafeealsharaa@yahoo.com
What processes are involved for a request to access data/document
The process takes approximately 10-22 days. Submit request. Review by committee. Approval and conditions. Sign the agreement. Data provided securely.
Comments
Data sharing will be conducted in accordance with ethical guidelines, ensuring participant confidentiality. Requests will be reviewed promptly, and support will be provided as needed throughout the process.