

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating the impacts of releasing the stiffness of hip adductor muscles on sacroiliac joint pain: a randomized clinical trial.

#### Protocol summary

##### Study aim

In our clinical experience, we have encountered numerous cases of sacroiliac joint pain, which also showed tightness of the hip adductor muscle. To answer the question of whether the release of the hip adductor muscles improves the treatment of sacroiliac joint pain, scientific sources were searched but no article was found in this field.

##### Design

A clinical trial with a control group, with parallel, non-blind, randomized with simple randomized groups on 40 patients

##### Settings and conduct

40 patients referred to the sports medicine department of Taleghani Hospital, with low back pain, who diagnosed sacroiliac joint pain and in the simultaneous examination of hip adductor muscle tightness are observed into two groups: A) Standard treatment of sacroiliac joint pain and release of hip adductor muscles and B) Standard treatment for sacroiliac joint pain will be divided. At the end of the treatment, the rate of change in sacroiliac joint pain in the two groups will be compared.

##### Participants/Inclusion and exclusion criteria

The sample size will be 40 people (20 people in group A, 20 people in group B). Inclusion criteria: 1-Low back pain less than 3 months 2- Sacroiliac joint disorder 3- Age 18-60 years Exclusion criteria: 1-Any contraindication for manual therapy

##### Intervention groups

People in 2 groups: A) Standard treatment of sacroiliac joint pain (including: daily heat therapy, needling painful areas (2 sessions per week), daily sacroiliac joint mobilization exercises) and release of hip adductor muscles and B) Standard treatment for sacroiliac joint pain will be divided.

##### Main outcome variables

At the beginning of each session and at the end of the treatment period, patients are evaluated for tenderness and sacroiliac joint pain and tenderness and stiffness of

hip adductors. Quality of life is assessed by an Oswestry questionnaire at the beginning and end of treatment.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201216049730N1**

Registration date: **2021-02-19, 1399/12/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-02-19, 1399/12/01**

Update count: **0**

##### Registration date

2021-02-19, 1399/12/01

##### Registrant information

##### Name

Mohammad Hassabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8869 2273

##### Email address

hassabi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-20, 1399/11/01

##### Expected recruitment end date

2021-07-23, 1400/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the impacts of releasing the stiffness of hip adductor muscles on sacroiliac joint pain: a randomized clinical trial.

**Public title**

The impacts of releasing the stiffness of hip adductor muscles on sacroiliac joint pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

People with low back pain less than 3 months Diagnosis of sacroiliac joint disorder (3 or more positive test) Equal true and functional length of lower limb (functional length: distance between umbilicus to distal of medial ankle, true length: distance between anterior superior iliac spine to distal of medial ankle) No history of severe trauma to the spine, pelvis, lower limbs, abdomen and chest during the last 12 months No history of spine, pelvic, lower limb, abdomen and chest surgery during the last 12 months Absence of localized lesion of the spine including tumor, infection and fracture Absence of known congenital pelvic and spinal disorders that restrict movement or impair examination Absence of known systemic arthropathy Absence of neuropathy Absence of metabolic disorders Absence of symptoms or evidence of radiculopathy Absence of pregnancy No history of receiving any treatment for sacroiliac joint pain in the last 3 months Women should not be in the first six months after delivery Women should not be post menopausal

**Exclusion criteria:**

Any musculoskeletal disorder of the lower extremities that interferes with movement or examination

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Study subjects are divided into two groups in a simple randomization with a ratio of one to one. In group A the stiffness of hip adductor muscles will be released in addition to the standard treatment of sacroiliac joint pain but group B will only receive the standard treatment of sacroiliac joint pain. The grouping will be written on pieces of paper, sealed in envelopes, and then given to the secretary. The secretary will randomly give one of the envelopes to the patient. The therapist will assign each patient to group A or B depending on the group written in the patient's envelope.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

**Street address**

Shahid Beheshti University of Medical Sciences, Arabi Ave., Yemen St., Tehran, Tehran Province

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Approval date**

2020-12-12, 1399/09/22

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1399.783

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

Sacroiliac joint pain and dysfunction: Painful touching of the sacroiliac joint and the positive test of 3 or more of the 6 tests diagnoses sacroiliac joint pain and dysfunction.

**ICD-10 code****ICD-10 code description****2****Description of health condition studied**

Hip adductor muscles: include Adductor Longus, Adductor Brevis, and Adductor Magnus. In this study, Adductor longus muscle is examined. Diagnosis of hip adductor disorder can be made by two imaging techniques, including ultrasound or MRI or clinical examination.

**ICD-10 code****ICD-10 code description****Primary outcomes**

## 1

### **Description**

Sacroiliac joint pain

### **Timepoint**

Before starting treatment, at the beginning of each treatment session, at the end of 4 treatment sessions

### **Method of measurement**

The patient is asked and recorded as 0 (painless) to 10 (worst possible pain) by the visual analog scale (VAS).

## 2

### **Description**

Sacroiliac joint tenderness

### **Timepoint**

Before starting treatment, at the beginning of each treatment session, at the end of 4 treatment sessions

### **Method of measurement**

Touch the sacroiliac joint to check for tenderness. Recording of tenderness information by a specialist doctor is done as follows: 1- No pain 2- Mild tenderness (causing pain with deep touch) 3- Moderate tenderness (causing pain with superficial touch) 4- Severe tenderness (severe reaction of the patient with superficial touch).

## **Secondary outcomes**

## 1

### **Description**

Quality of Life

### **Timepoint**

Before starting treatment, at the end of 4 sessions of treatment

### **Method of measurement**

Oswestry questionnaire

## 2

### **Description**

Adductor muscle tenderness

### **Timepoint**

Before starting treatment, at the beginning of each treatment session, at the end of 4 treatment sessions

### **Method of measurement**

Touch the junction of the adductor longus muscle to check for tenderness. Tenderness is recorded by a sports medicine specialist as 1- painless 2- mild tenderness (causing pain with deep touch) 3- moderate tenderness (causing pain with superficial touch) 4- severe tenderness (severe reaction of the patient with superficial touch).

## 3

### **Description**

Stiffness of adductor muscles

### **Timepoint**

Before starting treatment, at the beginning of each treatment session, at the end of 4 treatment sessions

### **Method of measurement**

Touch the length of the adductor longus muscle to check muscle stiffness. Stiffness is recorded by a sports medicine specialist in the form of 1- usual consistency 2- touch of stiffness 3- clear protrusion.

## **Intervention groups**

## 1

### **Description**

Intervention group: Group A, in addition to the standard treatment of sacroiliac joint pain, hip adductor muscles will be released. Duration of treatment: 4 sessions by the therapist (2 sessions per week) with daily exercises at home. Treatment of sacroiliac joint pain includes heat therapy for 5 minutes (daily), needling painful areas (2 sessions per week), sacroiliac joint mobilization exercises, each exercise 3 sets of 10 repetition, daily. Release of hip adductors including heat therapy for 5 minutes (daily), manual therapy (using friction massage and ischemic pressure) for 5 minutes (2 sessions per week), use of vibrator for 5 minutes (2 sessions per week), adductor stretching 30 seconds to the maximum range of motion whit out Pain, 3 repetitions, daily

### **Category**

Treatment - Devices

## 2

### **Description**

Control group: Intervention group: Group B who will receive standard treatment for sacroiliac joint pain. Duration of treatment: 4 sessions by the therapist (2 sessions per week) with daily exercises at home. Treatment of sacroiliac joint pain includes heat therapy for 5 minutes (daily), needling painful areas (2 sessions per week), sacroiliac joint mobilization exercises, each exercise 3 sets of 10 repetition, daily.

### **Category**

Treatment - Devices

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Ayatollah Taleghani Hospital

#### **Full name of responsible person**

Mohammad Hassabi

#### **Street address**

Ayatollah Taleghani Hospital, Arabi Ave., Yemen St., Tehran

#### **City**

Tehran

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#### **Postal code**

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#### **Phone**

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#### **Email**

hassabi@sbm.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Taleghani Hospital Development and Clinical Research Unit

**Street address**

Ayatollah Taleghani Hospital, Arabi Ave., Yemen Blvd., Tehran

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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**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyedeh Sara Shams

**Position**

Specialized Resident in Sports Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for updating data

#### Contact

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**Full name of responsible person**

Seyedeh Sara Shams

**Position**

Specialized Resident in Sports Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Sport Medicine

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**Email**

## 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 potential data is shared in the form of an article after unidentifiable individuals

### **When the data will become available and for how long**

Accessed since 2022

### **To whom data/document is available**

Researchers working in academic and scientific institutions

### **Under which criteria data/document could be used**

No analysis is allowed on the data

### **From where data/document is obtainable**

sarashams@gmail.com

### **What processes are involved for a request to access data/document**

To access the data, individuals must send a request to the inserted email and after receiving the necessary checks and if they are eligible, they will receive the requested data within a month.

### **Comments**