

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Comparison of the effect of manipulative techniques and exercise therapy on pain and function in patients with Sacroiliac joint dysfunction

#### Protocol summary

##### Summary

Our study compares the effect of exercise therapy and manipulation in Sacroiliac dysfunction. The patients will be divided in three groups randomly by the table of random numbers. One group will take manipulative techniques and exercise therapy. These patients will do exercises protocol for 3 months after taking manipulation techniques twice at the first session. The second group will take only two manipulative techniques and the patients will do self-mobilization techniques for 3 months daily. The third group will do only exercise for three months. All of the patients will be visited once a week for 3 months. The patients can use 100 mg Diclofenac a day if they have VAS > 5. The patients will be followed in 6, 12, 24 weeks after initiation of treatment. Severity of pain will be evaluated by Visual Analog Scale (VAS). Disability will be evaluated by ODI and Roland Morris Questionnaires and functional tests before and after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201412144409N4**

Registration date: **2015-02-01, 1393/11/12**

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

Last update:

Update count: **0**

##### Registration date

2015-02-01, 1393/11/12

##### Registrant information

##### Name

Parisa Nejati

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4480 0361

##### Email address

parisanejati@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2015-01-30, 1393/11/10

##### Expected recruitment end date

2015-10-23, 1394/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of manipulative techniques and exercise therapy on pain and function in patients with Sacroiliac joint dysfunction

##### Public title

Exercise therapy and manipulation in sacroiliac dysfunction

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age older than 20, low back pain or buttock pain at least for 3 months, no surgery in spine or pelvis in last year, not pregnant, at least 3 positive tests of following tests: Standing forward bending Test, Faber Test, Gilet Test, Yeoman Test, Ganselen Test, no severe osteoporosis or bone fracture, no radicular pain to below the knee, not using physical modalities in low back or buttock in last month, not using corticosteroid injection

in sacroiliac joint in last month, no sacroileitis or sacroiliac joint infection. Exclusion criteria: Exacerbation of pain that need a different therapeutic approach

#### **Age**

From **20 years** old to **100 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **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 Iran University of Medical Sciences

##### **Street address**

Vice chancellor for research, second floor, medicine faculty, Iran University of Medical Sciences, next to Milad tower, Hemmat highway

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2014-09-09, 1393/06/18

#### **Ethics committee reference number**

93-02-30-24400-103949

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Low back pain / Sacroiliac joint dysfunction

#### **ICD-10 code**

M-53.3 , M

#### **ICD-10 code description**

Sacrococcygeal disorders, not elsewhere classified low back pain

## **Primary outcomes**

### 1

#### **Description**

Pain

#### **Timepoint**

Before intervention, 6 , 12 and 24 weeks after intervention

#### **Method of measurement**

visual analog scale

### 2

#### **Description**

function and ability

#### **Timepoint**

before intervention, 6 , 12 and 24 weeks after intervention

#### **Method of measurement**

Rollandmorris, ODI questionnaires

## **Secondary outcomes**

### 1

#### **Description**

function

#### **Timepoint**

before intervention , 12, 24 weeks after intervention

#### **Method of measurement**

timed up and go test , Self-paced walk test

## **Intervention groups**

### 1

#### **Description**

After two techniques of manipulation, stretching exercises and core exercises and self- mobilization techniques will be educated to patient. They will do each exercise 3 times a day and repeat each exercise 5 times that long 20 seconds.

#### **Category**

Rehabilitation

### 2

#### **Description**

Second group take 2 techniques of manipulation. The patients will do self mobilization techniques 3 times a day without extra exercises for 3 months.

#### **Category**

Rehabilitation

### 3

#### **Description**

Third group take exercise without manipulation. They will do sacroiliac stretching exercises, core exercises, self mobilization exercises 3 times a day for 3 months. Each exercises longs for 20 seconds.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rasool Akram hospital

**Full name of responsible person**

Parisa Nejati, Assistant professor of sports medicine

**Street address**

Sports medicine department, Eight floor, Rasool Akram hospital, Niyayesh street, Satarkhan street

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences, Vice chancellor for research

**Full name of responsible person**

Dr Seyed Ali Javad Mousavi

**Street address**

Vice chancellor for research, fifth floor, central building, Iran University of Medical Sciences, next to Millad tower, Hemmat highway

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran University of Medical Sciences, Vice chancellor for research

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Parisa Nejati

**Position**

Assistant professor of sports medicine

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*