

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### The effect of dry needling technique on pain, disability and lower extremity kinematics during walking in patient with piriformis syndrome

#### Protocol summary

##### Study aim

The aim of this study was to examine the therapeutic aspect of the effect of the dry needling method on the symptoms of piriformis syndrome due to the specialty of this technique. Also in this study, the effect of piriformis dry needling technique on the changes in the range of motion of the lower limb joints while walking and the degree of kinematic variability of the hip, knee and ankle joints are investigated.

##### Design

In this study, patients with piriformis syndrome were first examined for pain and motion analysis during walking. Then, subjects will be divide into treatment and control groups. In the treatment group, patients receive three sessions of dry needling in one week, and the control group will not receive treatment. after then both groups are re-evaluated.

##### Settings and conduct

This study is single-blinded trial and will be carried out in the Clinic of Physiotherapy, Faculty of Rehabilitation Sciences of Iran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include pain in the buttocks or sciatica nerve, increased symptoms by sitting, tenderness at the the piriformis, tension-demand Maneuver increase symptoms. The patient's pain intensity between 3 to 6 and about atleast12 weeks from the onset of pain. exclusion criteria include contraindication of dry needling, pain in any lower limb joints, pregnancy, flat foot and limping .

##### Intervention groups

The study included two groups of control and treatment. In both groups, a preliminary assessment will be carried out. After that, the control group will not receive treatment for a week and then will assess. in control group after final assessment, physical therapy intervention will be done. the treatment group will receive dry needling technique, a three session per week on the piriformis muscle and under ultrasound and then

re-evaluated.

##### Main outcome variables

pain; range of motion; kinematic variability; disability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151026024729N2**

Registration date: **2018-08-24, 1397/06/02**

Registration timing: **prospective**

Last update: **2019-01-16, 1397/10/26**

Update count: **3**

##### Registration date

2018-08-24, 1397/06/02

##### Registrant information

##### Name

Abbas Tabatabaiee

##### Name of organization / entity

Iran University of Medical and Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2253 4001

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-27, 1397/06/05

##### Expected recruitment end date

2019-01-30, 1397/11/10

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of dry needling technique on pain, disability and lower extremity kinematics during walking in patient with piriformis syndrome

**Public title**

The effect of dry needling technique on walking in subjects with piriformis syndrome

**Purpose**

Treatment

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

buttock pain or radicular pain of sciatic nerve increase symptoms with sitting tenderness in piriformis muscle increase symptoms with tension-generated maneuver

**Exclusion criteria:**

contraindication of dry needling history of vertebral or lower extremity surgery pregnancy hip arthritis or pain lumbar discopathy or instability

**Age**

From **20 years** old to **40 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization using random block method is performed individually using sealed envelopes.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, evaluator do not know allocation and treatment effects.

**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**

Iran University of Medical Sciences, Shahid Hemmat Highway

**City**

tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Approval date**

2018-01-20, 1396/10/30

**Ethics committee reference number**

IR.IUMS.REC1396.9221342202

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

piriformis syndrome

**ICD-10 code**

S74.0

**ICD-10 code description**

Injury of sciatic nerve at hip and thigh level

**Primary outcomes****1****Description**

pain

**Timepoint**

Before first intervention, 72 hours and 7th days after the last treatment session

**Method of measurement**

visual analog scale

**Secondary outcomes****1****Description**

lower extremity kinematic

**Timepoint**

before first intervention and 72 hours after last treatment session

**Method of measurement**

motion analysis instrument

**2****Description**

pain pressure threshold

**Timepoint**

Before first intervention, 72 hours and 7th days after the last treatment session

**Method of measurement**

algometry

### 3

**Description**

disability

**Timepoint**

Before first intervention, 72 hours and 7th days after the last treatment session

**Method of measurement**

oswestry questionnaire

### 4

**Description**

internal and external range of motion of hip joint

**Timepoint**

Before first intervention, 72 hours and 7th days after the last treatment session

**Method of measurement**

by goniometry

## Intervention groups

### 1

**Description**

Control group: In this group, patients will not receive treatment for a week and after a week they will receive physiotherapy for the release of piriformis muscle.

**Category**

Rehabilitation

### 2

**Description**

Intervention group: In this group, people will be treated with dry needling. In this method, the needle is inserted into the piriformis muscle simultaneously with the help of an ultrasound apparatus, and it is rotated and returned for 60 seconds.

**Category**

Rehabilitation

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Physiotherapy Cilinic, Faculty of Rehabilitation, Iran University of Medical Sciences

**Full name of responsible person**

Abbas tabatabaiee

**Street address**

Physical therapy cilinic, Faculty of rehabilitation sciences., Madadkaran St., Shahnazari St., Madar Squar, Mirdamad, Tehran

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

kazem malakouti

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malakoutik@yahoo.com

**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

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Abbas tabatabaiee

**Position**

Ph.D Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

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Professor  
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## Person responsible for updating data

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**Latest degree**  
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**Other areas of specialty/work**  
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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

The total data from this study, including demographic information, primary and secondary outcomes are shared after participant being unidentifiable.

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

The start of the access period will be without a time limit from March of 2019.

### To whom data/document is available

The data from this study will only be available to researchers at academic institutions.

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

The data from this study will be available for use in secondary or review articles.

### From where data/document is obtainable

It will be possible for the researchers to access the documentation by email with a personal page on the site .E-mail address: pt.taba.a@gmail.com Researchgate address:  
[https://www.researchgate.net/profile/Abbas\\_Tabatabaiee](https://www.researchgate.net/profile/Abbas_Tabatabaiee)

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

All requests will be reviewed and answered within a maximum of 3 weeks.

### Comments