

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Comparing stretching exercise and compression exercise on electromyography of back muscles and leg muscles innervated by sciatic nerve during flexion relaxation phenomenon in patients suffering from low back pain having piriformis syndrome

#### Protocol summary

##### Study aim

To compare the effect of stretching and compression exercises on FRP (EMG) activity of lumbar muscles in patients with deep gluteal syndrome.

##### Design

A clinical trial with the control group, with parallel groups, single-blind, randomised, on 45 patients.

##### Settings and conduct

Among the patients with low back pain with piriformis syndrome referred to the special clinic (Mahdieh) of Kermanshah University of Medical Sciences who have piriformis syndrome, 45 people were randomly divided into one of the groups: 1- Piriformis stretching exercise, 2- Piriformis compression exercise. 3-control.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Patients with the deep gluteal syndrome, between 18 and 60 years of age. . Exclusion criteria are the diagnosis of other types of LBP such as disc herniation or spondylolisthesis, any pathology of the hip joint or any recent injury around the pelvis or knee, systemic disease that can affect the general condition of the participant such as severe diabetes and Obesity.

##### Intervention groups

Patients will be randomly assigned to one of the stretching, compression or control exercises. All treatment groups will receive 10 sessions of physiotherapy 3 times a week. All patients will receive a general physiotherapy treatment including 15 minutes of hot pack and 15 minutes of electrical stimulation of the nerve.

##### Main outcome variables

Before and after the intervention, electromyographic signals of the muscles are recorded. Pain and disability of patients before and after the intervention will be measured by the VAS scale and Oswestry index.

#### General information

##### Reason for update

Because of the interventional trial design and type of interventions, it is not possible to blind patients to treatment allocation. A principal assessor who was responsible for completing all outcome measures was blinded to the patients' allocation up to the end of the trial.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201604178035N4**  
Registration date: **2017-01-10, 1395/10/21**  
Registration timing: **prospective**

Last update: **2022-07-15, 1401/04/24**

Update count: **2**

##### Registration date

2017-01-10, 1395/10/21

##### Registrant information

##### Name

MohammadBagher Shamsi

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3838 4185

##### Email address

mshamsi@kums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Kermanshah University of Medical Sciences, Vice Chancellor for Research

**Expected recruitment start date**

2017-03-21, 1396/01/01

**Expected recruitment end date**

2021-12-30, 1400/10/09

**Actual recruitment start date**

2017-03-30, 1396/01/10

**Actual recruitment end date**

2021-12-30, 1400/10/09

**Trial completion date**

2021-12-30, 1400/10/09

**Scientific title**

Comparing stretching exercise and compression exercise on electromyography of back muscles and leg muscles innervated by sciatic nerve during flexion relaxation phenomenon in patients suffering from low back pain having piriformis syndrome

**Public title**

The study of stretching exercise and compression exercise on treatment of patients suffering from a specific kind of low back pain

**Purpose**

Treatment

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

1. The age range of the subjects is 18-69 years.
2. Patients must be approved by a physiotherapy specialist.
3. Willingness to participate in the study

**Exclusion criteria:**

Diagnosed with other types of Low Back Pain such as disc herniation or spondylolisthesis Patients with severe diabetes and obesity. Patients with hip or knee injuries.

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **45**

Actual sample size reached: **45**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

.Randomization is performed by Random Allocation computer software by a statistician which has no role in the study in such a way that a random order of three letters A (intervention 1), B (intervention 2) and C (control) in blocks will be made with random numbers 6 (For example ABCACA). Before starting the intervention, a research assistant puts the patients in one of the three intervention groups (stretching or compression exercises) or control (conventional physiotherapy).

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

A principal assessor who is responsible to complete all

outcome measures will be blinded to the patients' allocation.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714869914

**Approval date**

2016-06-08, 1395/03/19

**Ethics committee reference number**

kums.rec.1395.169

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

Low Back Pain

**ICD-10 code**

M54.9

**ICD-10 code description**

Dorsalgia, unspecified

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

Electromyographic amplitude of 1- Longissimus 2- Iliocostalis muscles 3- Gastrocnemius 4- Tibialis anterior

**Timepoint**

Before and after the intervention

**Method of measurement**

With surface electromyography

**Secondary outcomes**

## 1

### Description

Pain

### Timepoint

Before and after the intervention

### Method of measurement

Visual Analogue Scale (VAS)

## 2

### Description

Disability

### Timepoint

Before and after the intervention

### Method of measurement

Oswestry Disability Index

## Intervention groups

### 1

#### Description

Intervention group 1: Stretching Exercise-- Treatment will be three times a week and 10 sessions. patients will be lying flat in a supine position. They will be positioned their healthy foot up against a wall and held the position. They lie on their back and placed their ankle on the affected side over the other knee.

#### Category

Rehabilitation

### 2

#### Description

Intervention group 2: Compression exercises-- Treatment will be three times a week and 10 sessions. patients were sitting on top of a foam roller with the roll positioned on the back of the hip. They cross their affected leg on top of their other knee (to stretch the muscle) and slightly rolled on the lateral buttock area at the point of tenderness.

#### Category

Rehabilitation

### 3

#### Description

Control group: Received conventional physiotherapy-15 minutes of heat (Hot Pack)(8) and 15 minutes of conventional transcutaneous electrical nerve stimulation (TENS)

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Outpatient Clinic of Kermanshah University of Medical Sciences

#### Full name of responsible person

MohammadBagher Shamsi

#### Street address

Javanshir Street

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6714869914

#### Phone

+98 918 831 0161

#### Email

MBSHAMSI@YAHOO.COM

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr Behrooz Hamzeh

##### Street address

Vice Chancellor for Research of Kermanshah University of Medical Sciences , Shahid beheshti Boulevard,

##### City

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##### Province

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##### Postal code

6719851351

##### Phone

+98 83 3816 2315

##### Email

mbhamsi@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

**Full name of responsible person**

MohammadBagher Shamsi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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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)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable