

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 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

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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.

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget 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

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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

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Javanshir Street

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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,

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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

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**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