Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing stretching exercise and compression exercise on electeromyography 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

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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 electeromyography 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
Electromyografic amplitude of 1- Longisimus 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Dr Behrooz Hamzeh
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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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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