

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of the effectiveness of Radial Extracorporeal Shock wave Therapy and corticosteroid injection of piriformis muscle for treatment patients suffering of piriformis syndrome

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparison of Extracorporeal Shock Wave Therapy
Radial Muscle Effect with Corticosteroid Injection for the
Treatment of Patients with Piriformis Syndrome

Design

Clinical trial with intervention and control group with a
sample size of 35 people, in parallel group, single blind,
randomized with closed envelope

Settings and conduct

The study population is patients referred to physical
medicine and rehabilitation clinics of Firoozgar and
Rasoul Akram hospitals in Tehran. Patients are examined
by a specialist in physical medicine and rehabilitation
and entered into the plan if necessary. This study is a
randomized, single-blind clinical trial that is divided into
two groups by randomized closed envelope.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Chronic pain in Batuk at least 3 months
Age over 20 years Their pain intensity should be at least
5 out of 10 according to the Visual Analogue Scale
criteria Exclusion criteria: Symptoms of lumbar discus
Have a pregnancy or pregnancy plan Have a history of
disc surgery

Intervention groups

Shock therapy group and corticosteroid injection group

Main outcome variables

Severity of pain; quality of life

General information

Reason for update

According to similar studies, we increased the sample
size of the study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191027045252N1**
Registration date: **2020-01-10, 1398/10/20**

Last update: **2020-12-23, 1399/10/03**

Update count: **1**

Registration date

2020-01-10, 1398/10/20

Registrant information

Name

Arastoo Yousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 9437

Email address

arastoo.yousefi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Radial Extracorporeal
Shock wave Therapy and corticosteroid injection of
piriformis muscle for treatment patients suffering of
piriformis syndrome

Public title

Comparison of the efficacy of in vivo shock therapy with corticosteroid injection in the treatment of piriformis syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Chronic pain in Batuk, thigh and lower extremity for at least 3 months Patients must be over 20 years of age
 Screening of all patients for lumbar disc herniation and lumbar radiculopathy by MRI. Their pain intensity should be at least 5 out of 10 according to the Visual Analogue Scale criteria
Exclusion criteria:
 Symptoms of lumbar discus, coxopathy, mechanical or inflammatory disorders of the sacroiliac joint Any inflammatory, infectious, or pelvic abnormalities Have a pregnancy or pregnancy plan Have a history of disc surgery and any epidural block over the past 6 months. Patients who do not go for follow-up for any reason. Changes in the patient's treatment according to the physician's opinion or other treatment by the patient during the study

Age
From **20 years** old

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **35**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, in which each member of society has an equal and independent chance of being elected. The randomization procedure will use a randomized block with quadratic and binary blocks. Given the sample size of 35 people, 8 quadruple blocks and 1 binary blocks will be generated and numbered using the permutations method. Using the random number table, blocks will be placed together to form a sequence of patients assigned to treatment groups. Therefore, prior to selecting the participants, the type of treatment they receive will be unaware, and the random sequence generated during the study will be unpredictable.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the difference in the nature of the therapeutic intervention in the two groups, only the data analyzer will be blind.

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, Next to Milad Tower, Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-09-23, 1398/07/01

Ethics committee reference number

IR.IUMS.FMD.REC.1398.234

Health conditions studied

1

Description of health condition studied

Piriformis syndrome

ICD-10 code

G57.0

ICD-10 code description

Lesion of sciatic nerve

Primary outcomes

1

Description

Severity of pain

Timepoint

Baseline, 7, 30, 60, and 90 days after Intervention

Method of measurement

Visual Analogue Scale

2

Description

Quality of Life

Timepoint

Baseline and 30 days after Intervention

Method of measurement

36-Item Short Form Survey (SF-36) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients undergoing shockwave therapy, three sessions, each lasting 7 to 10 days. Shockwave is performed with the Storz Medical Shock Wave MP100. Each session of shockwave therapy with 2000 pulses and a total of 6000 pulses in three sessions, energy flux density equal to 0.18 mJ / mm², 5 Hz frequency, 4 bar pressure rate, Dose per treatment equal to 0.18 mJ / mm² = 2,000 360 mJ / mm² and Total energy dose (TED) equal to 1.080 J / mm².

Category

Treatment - Devices

2

Description

Control group: Patients treated with 40 mg methylprednisolone plus 1 cc lidocaine 1% undergo sonography in the piriformis muscle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Arastoo Yousefi

Street address

Firoozgar Hospital, Beh Afrin Ave, Karim Khan Street, Tehran, Iran

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2

Recruitment center

Name of recruitment center

Rasoul-e-Akram Hospital

Full name of responsible person

Arastoo Yousefi

Street address

Rasoul-e-Akram Hospital, Niayesh Ave., Sattarkhan, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevalian

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PR@iums.ac.ir

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

Arash Babaei

Position

استادیار

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

No 4, Banafshe Deadend, Second Deadend, Hoseini Ave, North Shahrdari, West Sarv Blvd, Saadat Abad, Tehran

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Arash Babaei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

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Iran University of Medical Sciences

Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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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 extent of pain relief can be shared according to the Visual Analogue Scale.

When the data will become available and for how long

Access started from 1400

To whom data/document is available

Study data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Access to the data will be allowed for epidemiological study and can be sent by email.

From where data/document is obtainable

To receive data, you could call 00989123190373 or contact arastoo.yousefi@gmail.com.

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

Individuals who request data, must provide their academic, Scientific documents and the reason for their requests to arastoo.yousefi@gmail.com.

Comments