

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparative Trial of Botulinum Toxin Type A and Methylprednisolone for The Treatment of Piriformis Syndrome

Protocol summary

Study aim

Comparison of the therapeutic effect of Ultrasound-Guided Injection of Botulinum Toxin Type A with Methylprednisolone in Piriformis Muscle Syndrome

Design

The study is a single-blinded (analyzers & assessor) clinical trial and the sampling will be done through a simple randomization method

Settings and conduct

Patients will be randomly divided into two groups. The research was carried out in physical medicine and rehabilitation clinic at Firoozgar hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients age : 20 years or older; Screening of patients for clinically significant Lumbar disk herniation or Lumbosacral radiculopathy by Magnetic Resonance Imaging; Trigger point and tenderness in their Gluteal area; Pain in their buttocks radiating toward their thigh or lower limb and increasing with prolonged sitting and walking and during bending; Increased pain through passive forced hip flexion, adduction, and internal rotation (FAIR position), and pain when the leg was flexed at the knee and the hip was passively and medially rotated (Freiberg test). Non-Inclusion criteria: Known allergy or sensitivity to botulinum toxin type A; Previous use of botulinum toxin type A or B; Current or planned pregnancy; Disorders affecting the Neuromuscular junction or Motor neuron disease, Neurologic deficits found during Electromyography.

Intervention groups

Intervention group : US-Guided Injection of 150 U of botulinum toxin type A (Dysport 50-U/ml solution) in 3 ml of normal saline. Control group: US-Guided injection of 1 cc methylprednisolone & 1 cc lidocaine 1%

Main outcome variables

Pain; Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191213045717N1**

Registration date: **2020-02-19, 1398/11/30**

Registration timing: **prospective**

Last update: **2020-02-19, 1398/11/30**

Update count: **0**

Registration date

2020-02-19, 1398/11/30

Registrant information

Name

Zeynab Shahabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-08-10, 1399/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Trial of Botulinum Toxin Type A and Methylprednisolone for The Treatment of Piriformis Syndrome		Placebo	Not used
		Assignment	Parallel
		Other design features	
Public title		Secondary Ids	
Effect of Botulinum Toxin Type A and Methylprednisolone in treatment of Piriformis Syndrome		empty	
Purpose		Ethics committees	
Treatment		1	
Inclusion/Exclusion criteria		Ethics committee	
Inclusion criteria:		Name of ethics committee	
The patients age : 20 years or older Screening of patients for clinically significant Lumbar disk herniation or Lumbosacral radiculopathy by Magnetic Resonance Imaging Trigger point and tenderness in their Gluteal area Pain in their buttocks radiating toward their thigh or lower limb and increasing with prolonged sitting and walking and during bending Increased pain through passive forced hip flexion, adduction, and internal rotation (FAIR position), and pain when the leg was flexed at the knee and the hip was passively and medially rotated (Freiberg test) Having pain for more than 3 months despite the conservative treatment and those whose individual minimum pain severity scores will be greater than 5 on a 10-point numeric rating scale (VAS criteria)		Ethics Committee of Iran University of Medical Science	
Exclusion criteria:		Street address	
Known allergy or sensitivity to botulinum toxin type A Previous use of botulinum toxin type A or B Current or planned pregnancy Disorders affecting the Neuromuscular junction or Motor neuron disease,Neurologic deficits found during Electromyography Administration of Amino- Glycosides or other drugs that interfere with Neuromuscular transmission Previous Micro- surgery or Macro-surgery for disc disease, and any Epidural block within 7 weeks of enrollment		Medical School, Iran University of Medical Sciences, Hemmat High way	
Age		City	
From 20 years old		Tehran	
Gender		Province	
Both		Tehran	
Phase		Postal code	
3		1449614535	
Groups that have been masked		Approval date	
- Participant - Outcome assessor - Data analyser		2019-12-03, 1398/09/12	
Sample size		Ethics committee reference number	
Target sample size: 30		IR.IUMS.FMD.REC.1398.387	
Randomization (investigator's opinion)		Health conditions studied	
Randomized		1	
Randomization description		Description of health condition studied	
Blocked randomization		piriformis muscle syndrome	
Blinding (investigator's opinion)		ICD-10 code	
Double blinded		S74.0	
Blinding description		ICD-10 code description	
At the begining of the study, all patients in the two groups will be injected in the same place of the body. Post-injection care is the same in all groups. It is worth noting that patients in any of the two groups are not aware of the content of the injections.		Injury of sciatic nerve at hip and thigh level	
		Primary outcomes	
		1	
		Description	
		The severity of Pain	
		Timepoint	
		Before treatment, 1th ,4th,8th &12th weeks after the end of treatment	
		Method of measurement	
		Visual Analog Scale (VAS)	
		2	
		Description	
		Quality of life	
		Timepoint	
		Before treatment,4th week after the end of treatment	
		Method of measurement	
		36-Item Short Form Health Survey (SF-36)	

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 150 U of botulinum toxin type A (Dysport 50-U/ml solution from Daryan Salamat Pharma Group) in 3 ml of normal saline using 22 gauge LP(Lumbar Puncture) needle under ultrasound guidance (lateral approach) will be injected in piriformis muscle.

Category

Treatment - Other

2

Description

Control group: 1 cc methylprednisolone (Exir Pharmaceutical Company, made in Iran) &1 cc lidocaine 1% (Aburaihan Pharmaceutical Company, made in Iran) using 22 gauge LP needle under ultrasound guidance (lateral approach) will be injected in piriformis muscle.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Educational Hospital

Full name of responsible person

Dr Tannaz Ahadi

Street address

Physical Medicine and Rehabilitation Department, Firouzgar Hospital, Behafarin street, Karim Khane Zand street, Tehran

City

Tehran

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1593748711

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H_Firoozgar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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5th floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway, Tehran

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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

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

Zeynab Shahabi

Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Dr Tannaz Ahadi

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Associate Professor of Physical Medicine and Rehabilitation

Latest degree

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Name of organization / entity

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Medical doctor

Other areas of specialty/work

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Street address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

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