

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Sono-guided Prolotherapy; Oxygen-ozone; corticosteroid therapy for the treatment of musculoskeletal Pain in physical and rehabilitation medicine: Interventional pain management for Piriformis: A Prospective, randomized, double-blind, Positive control, Multicenter Clinical Trial

Protocol summary

Study aim

Comparison of the effects of topical ozone and corticosteroid injections and prolotherapy in reducing pain due to various musculoskeletal disorders such as piriformis, a model for reducing pain

Design

This is a multicenter double-blind randomized clinical trial (patient and analyst)

Settings and conduct

The study was performed by four specialists in physical medicine and rehabilitation in four medical centers of Shohada and Imam Reza hospitals of Tabriz University of Medical Sciences, Rasoul Akram Hospital of Iran University of Medical Sciences and Iran Neuromuscular Center. In each group, after providing sterile conditions with Povidone-Iodine solution, anesthesia is performed locally with 1 cc of 2% lidocaine and 22 gage needle. For all patients, the injection will be performed under ultrasound guidance and using needle number 27 after aspiration and ensuring the correct placement of the needle.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Pain and the presence of trigger points at least 2 months ago. 2. VAS score up to 4. Exclusion criteria 1. Existence of radiculopathy 2. Appropriate imaging 3. Abscess, fibrosis 4. Existence of a history of physiotherapy in the last 2 months 5. The presence of trigger points in the gluteus medius muscle 6. Coagulation disorders 7. Pregnancy

Intervention groups

The first group receives prolotherapy and the second group receives corticosteroids and the third group receives ozone treatment.

Main outcome variables

Treatment, age, sex, occupation, level of education, weight, height, duration of illness, marked trauma, pain,

income level, overall clinical perception, overall patient perceptions, VAS, SF36, ROM, electrodiagnostic findings

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100827004641N15**

Registration date: **2020-08-04, 1399/05/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-04, 1399/05/14**

Update count: **0**

Registration date

2020-08-04, 1399/05/14

Registrant information

Name

Bina Eftekharsadat

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-18, 1398/10/28

Expected recruitment end date

2021-01-17, 1399/10/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Sono-guided Prolotherapy; Oxygen-ozone; corticosteroid therapy for the treatment of musculoskeletal Pain in physical and rehabilitation medicine: Interventional pain management for Piriformis: AProspective, randomized, double-blind, Positive control, Multicenter Clinical Trial

Public title

Sono-guided Prolotherapy/ Oxygen-ozone/ corticosteroid therapy for the treatment of musculoskeletal Pain in physical and rehabilitation medicine: Interventional pain management for Piriformis: AProspective, randomized, double-blind, Positive control, Multicenter Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pain and the presence of trigger points in the preformis area for at least 2 months VAS score up 4

Exclusion criteria:

Existence of radiculopathy based on clinical examination
Appropriate imaging if needed Abscess, fibrosis or any skin infection at the injection sitedisorders7. Pregnancy
Existence of a history of physiotherapy or injections in the last 2 months
The presence of trigger points in the gluteus medius muscle, which is adjacent to the piriformis
Coagulation

Age

From **46 years** old to **46 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

A block randomization method will be used to allocate participants to the groups with a 1:1:1 allocation using random allocation software (RAS) with block sizes of 3 and 6. Similar sealed envelopes will be used to conceal the allocation in a sequentially numbered opaque package

Blinding (investigator's opinion)

Triple blinded

Blinding description

Away from the patient's eye, prepare the injection material in the syringe and cover the syringes with an aluminum foil so that the person does not know the type of injection material.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

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Approval date

2020-01-18, 1398/10/28

Ethics committee reference number

IR.IUMS.REC.1398.1094

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

Piriformis syndrome

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Local injection of ozone

Timepoint

Baseline

Method of measurement

Specific indexes and sonographic findings

2**Description**

Corticosteroids

Timepoint

Before injection, one week later and two months after injection

Method of measurement

Specific indexes and sonographic findings

3

Description

Prolotherapy

Timepoint

Baseline

Method of measurement

Specific indexes and sonographic findings

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A

Category

Treatment - Drugs

2

Description

Intervention group B:

Category

Treatment - Drugs

3

Description

Intervention group c:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Shohda Educational and Medical Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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
 Tabriz 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available	paper
Study Protocol	When the data will become available and for how long
Yes - There is a plan to make this available	2020
Statistical Analysis Plan	To whom data/document is available
Yes - There is a plan to make this available	students
Informed Consent Form	Under which criteria data/document could be used
Yes - There is a plan to make this available	sharing for using
Clinical Study Report	From where data/document is obtainable
Yes - There is a plan to make this available	Tabriz university of medical sciences
Analytic Code	What processes are involved for a request to access data/document
Yes - There is a plan to make this available	email send
Data Dictionary	Comments
Yes - There is a plan to make this available	
Title and more details about the data/document	