

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Sono-guided prolotherapy/ oxygen-ozone/ corticosteroid therapy for the treatment of musculoskeletal pain in physical and rehabilitation medicine: Interventional pain management for trochanteric bursitis: a prospective, randomized, double-blind, positive control, multicenter clinical trial.

Protocol summary

Study aim

Comparison of the effects of ozone injection, corticosteroids and prolotherapy in reducing pain caused by various musculoskeletal disorders such as trochanteric bursitis, a model for reducing pain in these patients

Design

A double-blind randomized clinical trial (patient and analyst) was multicenter with a positive control group and in the group of patients with musculoskeletal disorders

Settings and conduct

Shohada and Imam Reza (AS) Educational and Medical Center affiliated to Tabriz University of Medical Sciences and Hazrat Rasoul Akram (AS) Hospital, Iran University of Medical Sciences and Iran Neuromuscular Center

Participants/Inclusion and exclusion criteria

Inclusion criteria: pain in the back of the trochanter that also has local tenderness. Exclusion criteria: the presence of pathology in the hip joint; Rheumatic disease; calcification at the injection site; any skin infection at the injection site; history of injection or on-site physiotherapy in the last 2 months; coagulation disorders; existence of lumbosacral radiculopathy.

Intervention groups

group A of ozone group B corticosteroid group C prolotherapy

Main outcome variables

ROM (Range of Motion); CGI (Clinical Global Impression); Visual Analogue Scale (VAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100827004641N16**

Registration date: **2020-08-24, 1399/06/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-24, 1399/06/03**

Update count: **0**

Registration date

2020-08-24, 1399/06/03

Registrant information

Name

Bina Eftekharsadat

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1330 3193

Email address

binasadat@tbzmed.ac.ir

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		physical medicine and rehabilitation).				
Scientific title	Sono-guided prolotherapy/ oxygen-ozone/ corticosteroid therapy for the treatment of musculoskeletal pain in physical and rehabilitation medicine: Interventional pain management for trochanteric bursitis: a prospective, 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 trochanteric bursitis: a prospective, randomized, double-blind, positive control, multicenter clinical trial.					
Purpose	Treatment					
Inclusion/Exclusion criteria	Inclusion criteria:					
	Pain in the back of the trochanter that also has local tenderness					
	Exclusion criteria:					
	The presence of pathology in the hip joint Rheumatic disease Calcification at the injection site Any skin infection at the injection site History of injection or on-site physiotherapy in the last 2 month Coagulation disorders Existence of lumbosacral radiculopathy					
Age	From 46 years old to 46 years old					
Gender	Both					
Phase	N/A					
Groups that have been masked	• Participant • Care provider					
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)	Double 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. Patients in each group will be evaluated by a physical medicine and rehabilitation assistant who is not aware of the type of injection before the injection, one week later, and two months after the injection. It should be noted that in each center, all injections are performed by a fixed person (specialist in					
Placebo	Not used					
Assignment	Parallel					
Other design features						
Secondary Ids						
empty						
Ethics committees						
<u>1</u>						
Ethics committee	Name of ethics committee					
	Iran University of Medical Sciences					
	Street address					
	Iran University of Medical Sciences, Hemmat Highway					
Ethics committee	City					
	Tehran					
	Province					
	Tehran					
Ethics committee	Postal code					
	5166614756					
	Approval date					
	2020-01-18, 1398/10/28					
Ethics committee reference number	IR.IUMS.REC.1398.1107					
Health conditions studied						
<u>1</u>						
Description of health condition studied	Trochanteric bursitis					
	ICD-10 code					
	M70.6					
	ICD-10 code description					
Description of health condition studied	Trochanteric bursitis					
Primary outcomes						
<u>1</u>						
Description	Pain intensity					
	Timepoint					
	Evaluating the visual analogue scale at the beginning of the study (before intervention) and 7 and 60 days after injection					
	Method of measurement					
Description	Visual analogue Scale					
<u>2</u>						
Description	Overall recovery rate					
	Timepoint					
	Evaluating the overall recovery rate at 7 and 60 days after injection					

Method of measurement

Patient Global Impression of Improvement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A :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. Any other medication should be avoided during treatment and follow-up will be one week after injection and two months after injection.

Category

Treatment - Drugs

2

Description

Intervention group B: 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. Any other medication should be avoided during treatment and follow-up will be one week after injection and two months after injection.

Category

Treatment - Drugs

3

Description

Intervention group C: 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. Any other medication should be avoided during treatment and follow-up will be one week after injection and two months after injection.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Educational and Medical Center

Full name of responsible person

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2

Recruitment center

Name of recruitment center

Imam Reza Medical Research & Training Hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

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4

Recruitment center

Name of recruitment center

Iran Neuromuscular Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran university of medical sciences

Full name of responsible person

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1449614535

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admins@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

Tabriz University of Medical Sciences

Full name of responsible person

Bina Eftekharsadat

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Position

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Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

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Latest degree

Specialist

Other areas of specialty/work

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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

paper

When the data will become available and for how long

2020

To whom data/document is available

students

Under which criteria data/document could be used

research

From where data/document is obtainable

Tabriz university of medical sciences

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

email

Comments