Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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Iran (Islamic Republic of)

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+98 41 1330 3193

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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 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 physical medicine and rehabilitation).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat Highway
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Province
Tehran
Postal code
5166614756
Approval date
2020-01-18, 1398/10/28
Ethics committee reference number
IR.IUMS.REC.1398.1107

Health conditions studied

1

Description of health condition studied
Trochanteric bursitis
ICD-10 code
M70.6
ICD-10 code description
Trochanteric bursitis

Primary outcomes

1

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
Visual analogue Scale

2

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
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2

Recruitment center
Name of recruitment center
Imam Reza Medical Research & Training Hospital
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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

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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
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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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
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