Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Ultrasound-guided Prolotherapy, Oxygen-ozone and corticosteroid injection for treatment of Pes Anserine bursitis: A randomized, double-blind, multi-center study.

Protocol summary

Study aim

To compare effect of ultrasound guided Corticosteroid, Ozone and Dextrose injection in patients with Pes Anserine bursitis. Non-surgical treatments are the first line in treatment of this condition. Corticosteroid injections are one of the treatment options for Pes Anserine bursitis. Recently, ozone and dextrose injections has been used as a treatment for these patients. These injections lack many of the disadvantages of corticosteroid injections.

Design

A phase 3, umulticenteral, randomized, double blinded, clinical trial with a parallel group design with one week and two months followed ups. 1 cc lidocaine 2% will be used for local anesthesia (skin) in all groups. Then, under sterile condition, one group will be received ultrasound guided Ozone injection from Pes Anserine burs at medial below knee. Injections will be performed with 25G needle and other groups will receive corticosteroid or dextrose prolotherapy.

Settings and conduct

patients with Pes Anserine bursitis referred to physiatrists clinics in Iran and Tabriz (University of Medical Sciences)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Tenderness in Pes Anserine bursa negative tests in physical examination for knee ligaments tear grade II or III Kellgren-Lawrence knee osteoarthritis Exclusion criteria: History of knee surgery or fracture Age less than 18 History of knee meniscus or ligament tear (ACL/PCL/MCL/LCL) Pregnancy Allergic reaction to Corticosteroid, Dextrose or Ozone Infection at the injection site Uncontrolled diabetes History of systemic inflammatory or connective tissue disease such as rheumatoid arthritis history of burs injections in the last six months History of gout

Intervention groups

Three ultrasound guided injection groups : 1.Corticosteroid, 2.Ozone 3.Dextrose

Main outcome variables

Visual Analogue Scale (VAS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151017024572N22**
Registration date: **2020-07-31, 1399/05/10**
Registration timing: **prospective**

Last update: **2020-07-31, 1399/05/10**
Update count: **0**

Registration date

2020-07-31, 1399/05/10

Registrant information

Name

Arash Babaei-Ghazani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-20, 1399/05/30

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Ultrasound-guided Prolotherapy, Oxygen-ozone and corticosteroid injection for treatment of Pes Anserine bursitis: A randomized, double-blind, multi-center study.

Public title
Ultrasound-guided Prolotherapy, Oxygen-ozone and corticosteroid injection for treatment of Pes Anserine bursitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Tenderness in Pes Anserine bursa location Negative physical examination for knee ligaments tear including valgus stress test Grade II or III Kellgren-Lawrence for knee osteoarthritis
Exclusion criteria:
History of knee surgery or fracture Less than 18 years old History of knee meniscus or ligaments tear (ACL/PCL/MCL/LCL) Pregnancy History of allergic reaction to Corticosteroid, Dextrose or Ozone Infection at the injection site Uncontrolled diabetes History of systemic inflammatory or connective tissue disease History of burs injections in the last six months History of gout
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly divided into three treatment groups using a table of random numbers and a centralized randomization method. In order to execute the randomization process to create a random sequence and to perform the random allocation process we will use RAS software which will be created by statisticians. Two hours before the patient's visit for injection, the person responsible for injection will contact the statistician by phone or text message and will ask her about the random assignment of the participant to a specific group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The injection material is prepared in the syringe without informing the patient and the syringes will be covered with an aluminum foil so that the participant does not know the type of injection material. Patients will be prohibited from receiving any NSAIDs or analgesics for a 15-day wash-out period prior to enrollment and intervention. Due to the different nature of ozone (gas), during the injection, there is a possibility that the injector will acknowledge the nature of this medical substance. The person responsible for outcome measures and the person responsible for the statistical analysis are also kept blind.
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, Next to Milad Tower, Shahid Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2019-12-29, 1398/10/08
Ethics committee reference number
IR.IUMS.REC.1398.1017

Health conditions studied

1

Description of health condition studied
Pes Anserine bursitis
ICD-10 code
M70.5
ICD-10 code description
Other bursitis of knee

Primary outcomes

1

Description
Visual Analog Scale (VAS)
Timepoint

Before intervention, 1 and 8 weeks after intervention

Method of measurement

Visual Analogue Scale Questionnaire

2

Description

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Timepoint

Before intervention and 1, 8 weeks after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group one: Corticosteroid, 40 mg Methylprednisolone, one time injection at the site of Pes Anserine bursa

Category

Treatment - Other

2

Description

Intervention group two: Ozone (O2-O3), 12 micro-gram, one time injection at the site of Pes Anserine bursa

Category

Treatment - Other

3

Description

Intervention group three: Prolotherapy (Dextrose 20 %), one time injection at the site of Pes Anserine bursa

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital, Iran University of Medical Sciences, Neuromusculoskeletal Research Center

Full name of responsible person

Arash Babaei-Ghazani

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Sattarkhat St, ShahrAra, Rasool Akram Hospital

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2

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Seyed Abas Motavallian

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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

Dr. Arash Babaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data will only be provided for journal during manuscript submission or for meta-analysis at the specific request of other individuals.

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

There is no further information

When the data will become available and for how long

There is no further information

To whom data/document is available

There is no further information

Under which criteria data/document could be used

There is no further information

From where data/document is obtainable

There is no further information

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

There is no further information

Comments