

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of ultrasound-guided topical ozone injection, corticosteroid injection and prolotherapy on pain intensity in patients with coccydynia: A prospective, double-blind, multicenter randomized clinical trial

Protocol summary

Study aim

To compare effect of ultrasound guided Corticosteroid, Ozone and Dextrose injection in patients with coccydynia

Design

Randomised, multicenter, double blinded, three arm parallel group clinical trial. RAS software will be used for randomization.

Settings and conduct

Phase 3 multi center, randomized, double-blind clinical trial, with parallel groups with follow-up one week and two months after injection in four different treatment 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 will be performed. Before injection, 2 cc of lidocaine 2% is used for local anesthesia of the skin and underlying tissues in all groups. Ozone is then injected under sterile conditions in a group of patients. The injection is with a 25 Gage needle and in the other two groups corticosteroids or dextrose will be injected under sterile conditions. 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: Diagnosis of coccydynia; age of 18-65 years; pain score ranging from 1 to 10 in visual analogue scale. Exclusion criteria: Tumors of the cauda equina; pelvic surgeries; Herniation of the lumbosacral disc.

Intervention groups

Intervention group 1:Ultrasound guided injection of Ozone; Intervention group 2:Ultrasound guided injection of corticosteroid; Intervention group 3:Ultrasound guided injection of Dextrose.

Main outcome variables

Pain intensity; overall recovery rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100827004641N17**

Registration date: **2020-08-26, 1399/06/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-26, 1399/06/05**

Update count: **0**

Registration date

2020-08-26, 1399/06/05

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

Scientific title
Comparison of the effect of ultrasound-guided topical ozone injection, corticosteroid injection and prolotherapy on pain intensity in patients with coccydynia: A prospective, double-blind, multicenter randomized clinical trial

Public title
Comparison of the effect of ozone, corticosteroid and prolotherapy in coccydynia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of coccydynia Age of 18-65 years Pain score ranging from 1 to 10 in visual analogue scale
Exclusion criteria:
Tumors of the cauda equina Pelvic surgery Herniation of the lumbosacral disc

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

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 a statistician. 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; Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2020-01-18, 1398/10/28

Ethics committee reference number

IR.IUMS.REC.1398.1016

Health conditions studied

1

Description of health condition studied

Coccydynia

ICD-10 code

M53.3

ICD-10 code description

Sacrococcygeal disorders, not elsewhere classified

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 one: Ozone (O2-O3), 12 micro-gram, one time ultrasound guided injection inside the sacrococcygeal area

Category

Treatment - Drugs

2

Description

Intervention group two: Corticosteroid, 40 mg Methylprednisolone, one time ultrasound guided injection inside the sacrococcygeal area

Category

Treatment - Drugs

3

Description

Intervention group three: Prolotherapy (Dextrose 20 %), one time ultrasound guided injection inside the sacrococcygeal area

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Medical Research & Training Hospital

Full name of responsible person

Bina Eftekharsadat

Street address

No 692; Golshar street; Ellgoli road

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3389 3337

Email

shohadahospital@tbzmed.ac.ir

2

Recruitment center

Name of recruitment center

Imam Reza Medical Research & Training Hospital

Full name of responsible person

Bina Eftekharsadat

Street address

Imam Reza Medical Research & Training Hospital; Golgasht avenue; Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3335 2073

Email

imamreza@tbzmed.ac.ir

3

Recruitment center

Name of recruitment center

Rasool Akram Medical Research & Training Hospital

Full name of responsible person

Bina Eftekharsadat

Street address

Hazrate Rasool Akram Hospital, Niayesh blvd, Satarkhan street

City

Tehran

Province

Tehran

Postal code

۱۴۳۵۶۱۳۱۳۱

Phone

+98 21 6435 1643

Email

imamreza@tbzmed.ac.ir

4

Recruitment center

Name of recruitment center

Iran Neuromuscular Center

Full name of responsible person

Bina Eftekharsadat

Street address

Hazrate Rasool Akram Hospital, Niayesh blvd, Satarkhan street

City

Tehran

Province

Tehran

Postal code

۱۴۳۵۶۱۳۱۳۱

Phone

+98 21 6435 1643

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Bina Eftekharsadat

Street address

Imam Reza Medical Research & Training Hospita;
Golgashat avenue; Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3337 1134

Email

pmrrc@tbzmed.ac.ir

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**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

Street address

Imam Reza Medical Research & Training Hospita;
Golgashat avenue; Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 1330 3193

Fax

+98 41 1337 3967

Email

binasadat@tbzmed.ac.ir

Person responsible for scientific 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

Street address

Rehabilitation ward, Imam Reza hospital, Golgasht
ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 1330 3193

Fax

+98 41 1337 3967

Email

binasadat@tbzmed.ac.ir

Person responsible for updating data

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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City

Tabriz

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East Azarbaijan

Postal code

5166614756

Phone

+98 41 1330 3193

Fax

+98 41 1337 3967

Email

binasadat@tbzmed.ac.ir

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