

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between local injection of dextrose 20% and corticosteroid in coccygodynia treatment: Clinical Randomized Trial

Protocol summary

Summary

This study is a randomized, double-blind, non-placebo controlled and single-center clinical trial. The aim of this study is to compare the efficacy of local Dextrose 20% injection as a prolotherapy solution and corticosteroid injection as a standard treatment for treating the coccygodynia. This study include 32 patients who have coccygodynia for over 2 months and their visual analogue scale pain score (VAS) is greater than or equal to four. Patients with coccyx dislocation, history of coccyx injection in 6 month ago and pain duration less than 2 months are not enrolled. Using block randomization, patients are categorized to one of two groups: 1. Local injection of dextrose 20% as an intervention group, 2. Local injection of corticosteroid (methylprednisolone) as a control group. Patients don't know about their group. All patients after giving ethical consent undergoing transrectal coccyx manipulation. In all patients after skin prep, anesthesia with 2 milliliter lidocaine 2% will be done. 8 cc of dextrose 20% in the first group and 1 milliliter methylprednisolone 40 milligrams in the second group inject topically and transdermally in the maximum tenderness area of coccyx. Both groups of patients are evaluated by resident of Physical medicine and rehabilitation who are not aware of the type of injection. This evaluation is performed before injection, a week later (by phone) and 1 month after the injection (by visit) via VAS (sitting, standing and supine). Finally, statistical comparison of results will perform.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080418687N1**

Registration date: **2014-09-03, 1393/06/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-03, 1393/06/12

Registrant information

Name

Lobat Majidi

Name of organization / entity

Department of physical medicine and rehabilitation,
Iran University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1679

Email address

lobat.majidi@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical
Sciences

Expected recruitment start date

2014-08-30, 1393/06/08

Expected recruitment end date

2014-10-30, 1393/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between local injection of dextrose 20% and
corticosteroid in coccygodynia treatment: Clinical
Randomized Trial

Public title

Clinical trial of comparison between dextrose and

corticosteroid injection on coccygodynia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: From 18 up to 75 years old patients; Pain duration more than 2 month, VAS(visual analog scale) is greater than or equal to 4 (In each of sitting, standing and supine position); No injection of the coccyx in 6 months ago; Coccyx dynamic radiography and patient history don't show coccyx dislocation. Exclusion criteria: Age less than 18 and more than 75 years old; History of coccyx injection in 6 month ago; Pain duration less than 2 months; Poorly controlled diabetes mellitus; History of rheumatic diseases; Concomitant low back pain; History of malignancy; Coccyx dislocation; Radiographic coccyx spicule; Bowel and bladder incontinence; Coagulopathy; Myelomeningocele and spina bifida; Skin abnormality in injection site; Concurrent pelvic floor physiotherapy.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Each participant is randomly assigned to a group via block randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran university of medical sciences

Street address

6th floor, Central Organization of university, Keshavarz Boulevard, Tehran

City

Tehran

Postal code

Approval date

2013-10-30, 1392/08/08

Ethics committee reference number

130/1645/92/5

Health conditions studied

1

Description of health condition studied

Coccygodynia

ICD-10 code

M53.3

ICD-10 code description

Sacrococcygeal disorders, not elsewhere classified, Coccygodynia

Primary outcomes

1

Description

VAS(visual analogue scales) in standing, sitting and supine position

Timepoint

before intervention, 1 week after intervention, 1 month after intervention

Method of measurement

How much pain patient can feel, what is the score of your pain? From 0 (no pain) up to 10 (the worst pain experienced in his/her life)? Patient shows its pain on 10 centimeters special Ruler.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, Trans rectal manipulation of the coccyx will be done. Then for anesthesia, 2 milliliter of lidocaine 2% inject on coccyx. After local anesthesia, 8 milliliter of dextrose 20 % inject in maximum tender point of the coccyx for prolotherapy at single dose.

Category

Treatment - Drugs

2

Description

Control group: First, Trans rectal manipulation of the coccyx will be done. Then for anesthesia, 2 milliliter of lidocaine 2% inject on coccyx. After local anesthesia, 1 milliliter of methylprednisolone 40 milligram inject in maximum tender point of coccyx at single dose, as a standard treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of physical medicine and rehabilitation,
Firoozgar Hospital

Full name of responsible person

Lobat Majidi, Resident of physical medicine and
rehabilitation

Street address

Firoozgar Hospital, Beh Afarin Street, Karim Khan e
Zand Avenue, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Iran University of
Medical Sciences

Full name of responsible person

Mehrdad Eftekhari MD

Street address

School of medicine, Iran University of Medical
Sciences

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Iran University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of physical medicine and rehabilitation,
Iran University of medical sciences

Full name of responsible person

lobat majidi

Position

physical medicine and rehabilitation resident, Doctor

of Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Physical medicine and rehabilitation specialist,
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty