

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of local corticosteroid injection in treatment of Coccydynia with and without ultrasound guidance

Protocol summary

Summary

1- Objectives: The aim of this trial is Comparison of the efficacy of local corticosteroid injection in treatment of Coccydynia with and without ultrasound guidance. 2- Design: it is a randomized control trial, single blinded, without placebo control, and clinical trial. 3- Setting and conduct the population under research are patients with coccydynia referring to physical medicine and rehabilitation clinic via an advertisement. The sample size is 30 people and in all patients, coccydynia is confirmed with superficial and intrarectal palpation. patients will be randomized to 2 groups of 15. 4- Participants including major eligibility criteria: inclusion criteria are Coccydynia and maximum tenderness be in streptococcal joint or tip of coccyx. Exclusion criteria including the patients who do not refer to clinic for follow up or getting other treatments. 5- Intervention: The intervention is local injection of teriamcinolin acetone in sacrococcygeal joint or tip of coccyx (depends on the point of maximum tenderness) with ultrasound guidance in the group and blind in the other group. 6- Main outcome measures (variables): The patients are followed and assessed of their pain 1 week, 4 and 8 weeks after the intervention with Visual Analogue Scale. Also, patient's quality of life will be tested with a valid questionnaire before and after the intervention. Sample collection and intervention will be done in 6 months. Blinding is done in patients groups. For both groups the Sonography probe is used, but for blind injection group, the Sonography guide will not be used for injection. The patients are informed prior the study and are aware that their injection may be with or without Sonography guide with their permission.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016123024621N5**

Registration date: **2017-02-10, 1395/11/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Tannaz Ahadi

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of local corticosteroid injection in treatment of Coccydynia with and without ultrasound guidance

Public title

Comparison of the efficacy of local corticosteroid injection in treatment of Coccydynia with and without ultrasound guidance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18 to 65 years; VAS scale equal to or more than 4 in any position of sitting, standing or supine lying; have not had coccyx injection or manipulation in past six months; the patients should not get pelvic floor physiotherapy during the treatment; maximum tenderness be in streptococcal joint or tip of coccyx. Exclusion criteria: the patients who do not refer to clinic for follow up or getting other treatments.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Hemmat Highway, Iran University of Medical Sciences

City

Tehran

Postal code

Approval date

2016-12-18, 1395/09/28

Ethics committee reference number

IR.IUMS.REC.1395.28537

Health conditions studied

1

Description of health condition studied

Coccygodynia

ICD-10 code

M53.3

ICD-10 code description

Sacrococcygeal disorders, not elsewhere classified

Primary outcomes

1

Description

Coccygeal pain

Timepoint

Before intervention, 1, 4 and 8 weeks after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Patient's quality of life

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

SF36 standard questionnaire

Intervention groups

1

Description

In the intervention group 2cc Lidocaine 2% and 1cc of 40 mg teriamcinolon acetonide under sonography guide will be injected locally at the point of maximum tenderness in sacrococcygeal joint or tip of coccyx. And patients are learned to do pelvic floor exercises regularly and also lifestyle modification.

Category

Other

2

Description

In the intervention group 2cc Lidocaine 2% and 1cc of 40 mg teriamcinolon acetonide will be blind injected locally at the point of maximum tenderness in sacrococcygeal joint or tip of coccyx. And patients are learned to do pelvic floor exercises regularly and also lifestyle modification.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgarl Hospital

Full name of responsible person

Mahdieh Asilian Mahabadi, Resident of physical medicine and rehabilitation

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Tannaz Ahadi

Position

Assistant professor of physical medicine and rehabilitation

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Seyed Ali Javad Mousavi

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Iran University of Medical Sciences, Hemmat Highway

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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

Vice chancellor for research, 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**

Iran University of Medical Sciences

Full name of responsible person

Mahdieh Asilian Mahabadi

Position

Resident of physical medicine and rehabilitation

Other areas of specialty/work**Street address**

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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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