Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 acetonide 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 dons 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

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Name of organization / entity

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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 Universiy 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 questionare

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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Firoozgar Hospital, Physical Medicine and Rehabilitation Clinic, Behafarin Street, Valiasr Square
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Sponsors / Funding sources

1

Sponsor
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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

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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