

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 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)

###### Phone

+98 21 8871 8207

###### Email address

ahadi.t@iums.ac.ir

##### 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

**Street address**

Firoozgar Hospital, Physical Medicine and Rehabilitation Clinic, Behafarin Street, Valiasr Square

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

Iran University of Medical Sciences

**Full name of responsible person**

Tannaz Ahadi

**Position**

Assistant professor of physical medicine and rehabilitation

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

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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

**Street address**

Iran University of Medical Sciences, Hemmat Highway

**City**

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, 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**

3th floor, No/ 18, Arab Hosseini St., Ashrafi Esfahani Highway

**City**

Tehran

**Postal code**

Tehran

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

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

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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*