

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness between steroid injection plus acupuncture and steroid injection alone in patients with coccydynia

#### Protocol summary

##### Study aim

comparison between steroid injection plus acupuncture and steroid injection alone in patients with coccydynia

##### Design

randomized clinical practice with control group, community based and pragmatic, with parallel groups

##### Settings and conduct

this study was performed in patients referred to Firoozgar hospital and analyzer is blind to information. patients are divided in to 2 groups by using block randomization method. interference in one group is injection in the most tender area and at the other group it is done with injection plus 8 sessions of acupuncture.

##### Participants/Inclusion and exclusion criteria

entering criteria: patients between 18 -75 years old, chronic coccyx pain at least 2 month, VAS > 4, have not had any injection or manipulation in the past 6 month  
exiting criteria: age 18> or <75, history of injection or manipulation in the past 6 month, pain duration less than 2 month, VAS<4, history of poor control diabet or rheumatologic disorder, any low back pain radiating to sacrococcygeal area, history of any kind of canser, coccyx dislocation, acute fissure, coagulopathy, history of myelomeningocele and spinabifida, skin disease in the injection area, biofeedback therapy for other kind of pelvic muscle disorder.

##### Intervention groups

paitients who have had pain in coccyx more than 2 month and have VAS greater or equal 4 , and their history and physical examinations confirm the diagnosis, entering the experiment. then they divided in to 2 groups by using block randomization method. interference in one group is injection in the most tender area and teaching pelvic floor exercise and at the other group it is done with all above said plus 8 sessions of acupuncture.

##### Main outcome variables

mean pain intensity in patients in interference and control groups

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180205038629N1**

Registration date: **2018-10-22, 1397/07/30**

Registration timing: **retrospective**

Last update: **2018-10-22, 1397/07/30**

Update count: **0**

##### Registration date

2018-10-22, 1397/07/30

##### Registrant information

##### Name

Mahdieh Motaghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8897 8016

##### Email address

hoda.motaghi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-16, 1396/06/25

##### Expected recruitment end date

2018-04-25, 1397/02/05

##### Actual recruitment start date

2018-01-22, 1396/11/02

##### Actual recruitment end date

2018-05-24, 1397/03/03

##### Trial completion date

empty

##### Scientific title

Comparison of the effectiveness between steroid injection plus acupuncture and steroid injection alone in patients with coccydynia

**Public title**

Effect of acupuncture in coccydynia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with chronic pain in coccyx more than 2 month VAS more than or equal to 4 They haven't had injection or manipulation in past 6 month

**Exclusion criteria:**

History of injection or manipulation of coccyx in past 6 month Duration of pain less than 2 month VAS less than 4 History of poor control diabete History of rheumatologic disorders Existence of any kind of radicular pain in sacrococcygeal region History of cancer Dislocation of coccyx Acute fissure Coagulopathy History of myelomeningocele or spina bifida Skin disorders in the site of injection Concurrent biofeedback therapy in pelvic floor muscle

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **36**

Actual sample size reached: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients were included in the study using randomized sequencing (block randomization )

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The analyser dose not know about which data is in the group of cases or controls

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethic committee of Iran university of medical sciences

**Street address**

Firoozgar hospital, Behafarin ave, Karimkhan blvd, Tehran town

**City**

Tehran

**Province**

Tehran

**Postal code**

1593747811

**Approval date**

2018-01-15, 1396/10/25

**Ethics committee reference number**

2612

**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**

VAS score about patients pain

**Timepoint**

at the beginning, after 1 month and 3 month

**Method of measurement**

SF36 questionnaire, VAS score

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: acupuncture ( 8 sessions, twice a week) plus steroid injection in coccyx

**Category**

Treatment - Other

**2****Description**

Control group: steroid injection in coccyx

**Category**

Treatment - Other

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Firoozgar hospital

**Full name of responsible person**

Mahdieh Motaghi

**Street address**

Firoozgar hospital, Behafarin ave, karimkhan blv

**City**

Tehran

**Province**

Tehran

**Postal code**

1593747811

**Phone**

+98 21 8214 1229

**Email**

hoda.motaghi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyyed Kazem Malakooti University research deputy

**Street address**

Iran uni, Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 86701

**Email**

admins@iums.ac.ir

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Mahdie Motaghi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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**Province**

Tehran

**Postal code**

1593747811

**Phone**

+98 21 8214 1229

**Email**

hoda.motaghi@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Tannaz Ahadi

**Position**

associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

Firoozgar hos, Behafarin ave, Karimkhan blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1593747811

**Phone**

+98 21 8214 1600

**Email**

tannaz.ahadi@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mahdieh Motaghi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

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**Postal code**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

there is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available