

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

Street address

Firoozgar hospital, Behafarin ave, Karimkhan blv

City

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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

Firoozgar hos, Behafarin ave, Karimkhan blvd

City

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Province

Tehran

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Email

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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