Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 canser 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

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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

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Iran uni, Hemmat highway

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1449614535

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adminsite@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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Person responsible for scientific inquiries

Contact

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Position
associate professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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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