Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Radial Extracorporeal Shockwave and Corticosteroid Injection In The Treatment of Patients With Coccydynia

Protocol summary

Study aim
Compare the effect of extarcorporeal radial shockwave and corticosteroid injection in patients with coccydynia
Design
Randomized, with control group, single blinded
Settings and conduct
Patients with coccydynia referred to physical medicine and rehabilitation clinics of Firoozgar hospital randomly assigned into two groups using allocation sequence numbered sealed envelops. physician assessing the outcome measures and data analyser will be blinded.
Participants/Inclusion and exclusion criteria
Inclusion criteria: coccydynia more than 2 months, Visual Analog Scale (VAS) equal or greater than 4 in standing, sitting, and supine positions Exclusion criteria: history of coccyx dislocation, history of fecal and urine incontinency, local infection in coccyx area, history of coccygeal manipulation or injection within last 6 months, poor controlled diabetes mellitus, malignancy, anticoagulant use, low back pain, myelomeningocele, spina bifida, rheumatologic diseases
Intervention groups
Intervention group: radial shock wave Control group: local corticosteroid injection
Main outcome variables
Pain intensity in standing, sitting and supine positions; Quality of life ; Effect of pain on daily activities and leisure

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20151020024621N8**
Registration date: **2019-11-16, 1398/08/25**
Registration timing: **prospective**
Last update: **2019-11-16, 1398/08/25**
Update count: **0**
Registration date
2019-11-16, 1398/08/25

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-11-21, 1398/08/30
Expected recruitment end date
2020-01-20, 1398/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Radial Extracorporeal Shockwave and Corticosteroid Injection In The Treatment of Patients With Coccydynia

Public title
Effect of Shockwave and Corticosteroid in Coccydynia
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
Coccydynia more than 2 months Visual Analog Scale (VAS) equal or greater than 4
Exclusion criteria:
History of coccyx dislocation History of fecal and urine incontinency Local infection in coccyx area History of coccygeal manipulation or injection within last 6 months Poor controlled diabetes mellitus Malignancy Anticoagulant use Low back pain Myelomeningocele Spina bifida Rheumatologic diseases

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants who will meet the inclusion criteria will assign into two groups using randomly generated treatment allocations produced by an analyst who is not engaged with the enrollment. Sealed opaque envelopes is a method of allocation concealment.Random allocations will be recorded on the card and cards will be placed in the envelops. During the enrollment of each participant, one envelop will be opened and allocation of that participant will be disclosed.

Blinding (investigator's opinion)
Single blinded

Blinding description
physician who is in charge of outcome assessment and data analyser are blinded. blinding of participants could not be done dute the nature of interventions.

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
Iran University of Medical Sciences , Hemmat highway, Tehran

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Tehran

Province
Tehran

Postal code
1449614535

Approval date
2018-10-28, 1397/08/06

Ethics committee reference number
IR.IUMS.FMD.REC.1397.088

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
Pain intensity in standing, sitting and supine positions

Timepoint
Before and 1 week, 1 month, 2 months, 6 months after treatment

Method of measurement
visual analog scale (VAS)

2

Description
Quality of life

Timepoint
Before and one month after the treatment

Method of measurement
SF-36 questionnaire

3

Description
Effect of pain on daily activity and leisure time

Timepoint
Before and one month after treatment

Method of measurement
Dallas pain questionnaire

Secondary outcomes

1

Description
side effects

Timepoint
one week and one month after treatment

Method of measurement
physical examination

Intervention groups

1

Description
Interv̌ention group: Radial Shock wave in coccyx area consecutive 3 sessions weekly with 2000 pulse, 5 Hz frequency, Energy bar 3-4
Category
Treatment - Devices

2

Description
Control group: corticosteroid injection : 1 cc triamcinolon acetonide in maximum tender area in sacrococcygeal joint or tip of coccyx
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Sima Hosseinverdi
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Sponsors / Funding sources

1

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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
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
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Sima Hosseinverdi
Position
Resident
Latest degree
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Specialist
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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 further 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