

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

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

Protocol summary

Study aim

Compare the effect of extracorporeal 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 envelopes. 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

Name

Tannaz Ahadi

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

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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 envelopes. 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 due to 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

City

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

InterVention 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

Street address

Firoozgar Hospital ,Valadi alley, Valiasr street, Tehran

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

Full name of responsible person

Sima Hosseinverdi

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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Full name of responsible person

Tannaz Ahadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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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 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