

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+98 21 8871 8207

###### Email address

ahadi.t@iums.ac.ir

##### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1593747811

##### Phone

+98 21 8214 1229

##### Email

simahosseinverdi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Seyed Abas Motevalian

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Iran University of Medical sciences, Hemmet highway, Tehran

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##### Province

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##### Postal code

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##### Phone

+98 21 8670 4704

#### Email

amotevalian@yahoo.com

#### 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

##### Street address

Firoozgar Hospital, Valadi alley, Valiasr street, Tehran

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Email

simahosseinverdi@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

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## Person responsible for updating data

### 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  
**Street address**  
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simahosseiverdi@gmail.com

## 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