Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of Extracorporeal Shock Wave Therapy on Pain in Patients with Chronic Refractory Coccydynia

Protocol summary

Summary

To determine the effects of ECSWT on pain in patients with chronic coccydynia, in a single blind interventional clinical study, including patients with chronic coccydynia without acute fracture, patients will be randomly divide into intervention and control groups. All the patients in the intervention group will receive ECSWT with radial probe delivering 3,000 shock waves of 2 Bar per session with 21 Hz frequency directed to the coccyx in 4 sessions by 1 week intervals. The control group will be treated with one episode of steroid injection (Triamcinolone 40mg) instead. The pain severity will be recorded according to VAS scale before beginning of therapy and 1 and 6 months after ending the therapy. All data will studied with a person who has no information about the case or control groups. Each group contains 10 patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071921673N2**
Registration date: **2015-07-27, 1394/05/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-27, 1394/05/05

Registrant information

Name
Mahboobeh Mashayekhi Asl
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Isfahan University of Medical Sciences

Expected recruitment start date

2014-05-01, 1393/02/11

Expected recruitment end date

2015-04-30, 1394/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Extracorporeal Shock Wave Therapy on Pain in Patients with Chronic Refractory Coccydynia

Public title

Effects of Extracorporeal Shock Wave Therapy on Pain in Patients with Chronic Refractory Coccydynia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: At least 18y old; At least 24-month history of pain in coccygeal area being triggered by changing position without radiation; Had received conservative therapies for at least 1 year without recovery; Exclusion criteria: Acute coccygeal fractures; Tumors; Osteomyelitis; Pilonidal abscess; Genitourinary incontinency; Neurologic deficit; Opium addiction;

Age

From **18 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Daneshgah st.
City
Isfahan
Postal code
Approval date
2015-07-11, 1394/04/20
Ethics committee reference number
IR.MUI.REC.1394.1.048

Health conditions studied

1

Description of health condition studied
Coccygodynia
ICD-10 code
M53.3
ICD-10 code description
Sacrococcygeal disorders, not elsewhere classified

Primary outcomes

1

Description
Pain severity
Timepoint
Before Intervention, 4w after last intervention, 6m after last intervention
Method of measurement
VAS score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: ECSWT with radial probe delivering 3,000 shock waves per session of 2 Bar with 21 Hz frequency directed to the coccyx, 4 session of ECSWT with 1 week intervals.
Category
Treatment - Devices

2

Description
Control: Triamcinolone 40mg, Ampule, Injection, only once.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Kashany Hospital
Full name of responsible person
Mahboobeh Mashayekhi Asl
Street address
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Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan Univercity of Medical Sciences
Full name of responsible person
Shila Haghighat M.D.
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Physical medicine and rehabilation Group, Medical Department, Isfahan University of Medical Sciences, Daneshgah St.
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan Univercity of Medical Sciences
Proportion provided by this source
100
Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Resident, Phisycal Medicine and Rehabilitation

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty