

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

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Email address

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Shila Haghighat M.D.

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Physical medicine and rehabilitation 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 University 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

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Person responsible for general inquiries

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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