

# 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

+98 31 3443 9361

###### Email address

h.ghasemi@eng.ui.ac.ir

###### 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

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Full name of responsible person

Shila Haghighat M.D.

##### Street address

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

### Contact

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## Person responsible for updating data

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Isfahan Univercity of Medical Sciences  
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Shila Haghighat  
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Physiatrists  
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**City**

## 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*