

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effectiveness of of intra-articular sacroiliac injection in patients with sacroiliac pain

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of of intra-articular sacroiliac injection in patients with sacroiliac pain

##### Design

Clinical trial without control group, phase 3 on 27 patients

##### Settings and conduct

This study is performed in Kashani Hospital in Isfahan. Selected patients treated with 10 mg solution of triamcinolone stanoid intra-sacroiliac joint under fluoroscopic guidance using needle 26. Patients' pain is measured by a questionnaire at 2, 4 weeks and 6 months later.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age range 70-21 years, pain in the sacroiliac and lumbar joint, pain more than 6 months, at least 50% reduction in pain after 30 minutes of intra-articular diagnostic block with 0.5 ml of 2% lidocaine, consent Written to enter the study. Exclusion criteria: Existence of special conditions that are contraindicated for intra-articular injection, presence of diseases such as vertebral disc disease and vertebral disc herniation, radiculopathy, neuropathy, treatment with anticoagulants

##### Intervention groups

Intervention group: Patients in this group are treated with 10 mg solution of triamcinolone stanoid intra-sacroiliac joint under fluoroscopic guidance using needle # 26. Patients' pain is measured by a questionnaire at 2, 4 weeks and 6 months later.

##### Main outcome variables

Patients' back pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200217046523N4**

Registration date: **2020-10-14, 1399/07/23**

Registration timing: **prospective**

Last update: **2020-10-14, 1399/07/23**

Update count: **0**

##### Registration date

2020-10-14, 1399/07/23

##### Registrant information

###### Name

Aryan Rafiee Zadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3837 1582

###### Email address

rafieezadeh.a@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-04, 1399/08/14

##### Expected recruitment end date

2020-11-14, 1399/08/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effectiveness of of intra-articular sacroiliac injection in patients with sacroiliac pain

##### Public title

Corticosteroid injection into the sacroiliac joint

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age range 70-21 years Pain in the sacroiliac and lumbar region Pain for more than 6 months Minimum 50% reduction in pain after 30 minutes of intra-articular diagnostic block with 0.5 ml of 2% lidocaine Written consent to enter the study

### Exclusion criteria:

There are special conditions that are contraindicated for intra-articular injection Existence of diseases such as vertebral disc diseases and vertebral disc herniation Radiculopathy Neuropathy Treatment with anticoagulants

## Age

From **21 years** old to **70 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Esfahan university of Medical sciences

##### Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

۸۱۳۷۸۶۶۵۱۵

#### Approval date

2018-10-27, 1397/08/05

#### Ethics committee reference number

IR.MUI.MED.REC.1397.114

## Health conditions studied

### 1

#### Description of health condition studied

Sacroiliac joint pain

#### ICD-10 code

S33.6

#### ICD-10 code description

Sprain of sacroiliac joint

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

At 2, 4 weeks and 6 months after the intervention

#### Method of measurement

VAS questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients in this group are treated with 10 mg solution of triamcinolone steroid intra-sacroiliac joint under fluoroscopic guidance using needle # 26. Patients' pain is measured by a questionnaire at 2, 4 weeks and 6 months later.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kashani Hospital

##### Full name of responsible person

Ali Andalib

##### Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 0042

##### Email

ali\_andelib@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo

**Street address**

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0042

**Email**

haghjoo.sh@med.mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ali Andalib

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

**Street address**

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3337 7986

**Email**

ali\_andelib@yahoo.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ali Andalib

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

**Street address**

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3337 7986

**Email**

ali\_andelib@yahoo.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ali Andalib

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

**Street address**

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3337 7986

**Email**

ali\_andelib@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Yes - There is a plan to make this available  
**Informed Consent Form**  
Yes - There is a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available  
**Analytic Code**  
Yes - There is a plan to make this available  
**Data Dictionary**  
Yes - There is a plan to make this available  
**Title and more details about the data/document**  
All data can be shared after people have requested.  
**When the data will become available and for how**

**long**  
Six months after publishing the results.  
**To whom data/document is available**  
Academic researchers  
**Under which criteria data/document could be used**  
Scientific uses  
**From where data/document is obtainable**  
Isfahan University of Medical Sciences website  
**What processes are involved for a request to access data/document**  
Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.  
**Comments**