Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of topical injection of dextrose and corticosteroids under ultrasound guidance in the treatment of sacroiliac joint inflammation, a Clinical trial

Protocol summary

Study aim

The aim of this study is to compare the effects of ultrasound-guided injections of corticosteroid and Prolotherapy in the treatment of sacroiliac joint inflammation.

Design

A randomized (randomized blocking method), double blinded (patients and analyzers), clinical trial with a parallel group design of 40 patients referred to physical medicine and rehabilitation clinic at Firoozgar hospital, enrolled between 2015 and 2016, and followed for 8 weeks.

Settings and conduct

patients will be randomly divided to two groups of twenty. For randomization we will use randomized blocking method. The place of execution is physical medicine and rehabilitation clinic at Firoozgar hospital.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of sacroiliac (SI) joint pain, failure to respond to medication for one month, having a score of at least 4 in the Visual Analog Scale (VAS) criteria. Exclusion criteria: Malignancy, fractures, inflammatory arthritis, infections, fibromyalgia.

Intervention groups

After providing sterile conditions for injection, in one group, 2.5 ml containing 40 mg of triamcinolone and 2 cc of lidocaine and in other group, 2.5 cc of dextrose 20% and 2 cc of lidocaine, ultrasound-guided injected in the SIJ space. In both groups, physical therapy, including ROM exercises, stretching and isometric exercises will be taught to patients.

Main outcome variables

The severity of symptoms by Visual Analog Scale (VAS); The severity of symptoms and functional limitations in chronic low back pain by Dallas questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170910036107N2**
Registration date: **2018-02-07, 1396/11/18**
Registration timing: **retrospective**

Last update: **2018-02-07, 1396/11/18**
Update count: **0**

Registration date

2018-02-07, 1396/11/18

Registrant information

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Name of organization / entity
Iran university of medical science and health services
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-07-25, 1396/05/03

Expected recruitment end date

2017-12-24, 1396/10/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of topical injection of dextrose and corticosteroids under ultrasound guidance in the treatment of sacroiliac joint inflammation, a Clinical trial

Public title

Effect of topical injection of dextrose and corticosteroids in treatment of sacroiliac joint inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of sacroiliac (SI) joint pain Failure to respond to medication for one month Having a score of at least 4 in the Visual Analog Scale (VAS) criteria

Exclusion criteria:

Malignancy Fractures Inflammatory arthritis Infections Fibromyalgia

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: block, Unit of randomization: individual, Tools used in randomization such as table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blind study in which patients and outcomes analyzer are blinded. In order to blind the patient, it is said that both materials are effective for treatment, but the type of substance is not mentioned for patients when its injected. In order to blind the analyzer, the persons responsible for injection and data collection are different from the outcome assessors.

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 Science

Street address

Medical faculty, Iran University of Medical Sience, Hemmat High way

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2017-07-24, 1396/05/02

Ethics committee reference number

1396.9411524009

Health conditions studied

1

Description of health condition studied

Inflammation of the sacroiliac joint

ICD-10 code

M46.1

ICD-10 code description

Sacroiliitis, not elsewhere classified

Primary outcomes

1

Description

The severity of symptoms

Timepoint

Before injection, 2 weeks and 8 weeks after injection

Method of measurement

Visual Analog Scale (VAS)

2

Description

The severity of symptoms and functional limitations in chronic low back pain.

Timepoint

Before injection, 2 weeks and 8 weeks after injection

Method of measurement

Dallas questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Ultrasound-guided injection of Dexterose 20% in the SIJ space
Category
Treatment - Drugs

2

Description
Control group: Ultrasound-guided injection of corticosteroid in the SIJ space
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Physical Medicine and Rehabilitation,Firoozgar Hospital
Full name of responsible person
Gholam Reza Raissi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Javad Mousavi
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5th floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway,
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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
Neuromusculoskeletal Research Center
Full name of responsible person
Gholam Reza Raissi
Position
Associate professor of Physical Medicine and Rehabilitation
Latest degree
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Person responsible for updating data

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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 the patient's data can be shared with privacy in regard to patients name
When the data will become available and for how long
Start accessing 6 months after publishing the results.
To whom data/document is available
For scholars working in academic centers.
Under which criteria data/document could be used
It can be analyzed and printed by other people by mentioning the source.
From where data/document is obtainable
Dr. Naseh Yousefi, 989124261524, www.nasehusefi@gmail.com.
What processes are involved for a request to access data/document
Upon authentication, data is provided to the individual.
Comments