Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparing the effectiveness of ultrasound-guided versus fluoroscopy-guided sacroiliac joint intra-articular injection in patients with sacroiliac joint disorders

Protocol summary

Study aim

Comparison of the success rate of fluoroscopy and ultrasound guide for sacroiliac joint injection in patients with chronic low back pain

Design

A single-blinded, randomized clinical trial with parallel groups design of 122 patients

Settings and conduct

This study is a clinical trial in pain clinics of Shafa, Razi and velayat hospitals in Rasht. Patients will be selected through convenience sampling and by using randomized blocks will be divided into ultrasound and fluoroscopy groups.The injected drug is Rupivacaine 0.2% (manufacturer: L Molteni,Italy) and methylprednisolone 40milligrams (manufacturer:Caspian tamin Co, made in Iran), which will be done by Sharp curved needle Number 22. Ultrasound device type, 2.5 to 8 MHz ultrasound probe and fluoroscopic images will be obtained through General Electric DEC 9900 C-rm. Patients in both groups will be compared in terms of pain intensity in passive and elective mode based on a numerical ranking scale of 10-point (zero= no symptoms to 10= worst imaginable symptoms) at the times: before the procedures,zero,15 minutes and 24 hours after procedures.The duration of the procedures and complications will also be recorded as well.This study is single-blinded, patients are aware of their treatment and the evaluator is unaware.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients nominated for sacroiliac joint injection due to being positive in at least 4 out of 7 clinical examinations, Average pain at least 3 out of 10 in NRS, Persistent pain for 6 weeks and not responding to conservative treatments. Exclusion criteria: Indistinguishable distinction between sacroiliac joint pain and L5/S1 fastogenic back pain

Intervention groups

Ultrasound group: Sacroiliac joint injection with ultrasound guide Fluoroscopic group: Fluoroscopy with sacroiliac guide

Main outcome variables

Pain intensity, Duration of the procedure, Complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170314033069N4**
Registration date: **2021-01-13, 1399/10/24**
Registration timing: **prospective**

Last update: **2021-01-13, 1399/10/24**
Update count: **0**

Registration date

2021-01-13, 1399/10/24

Registrant information

Name

Gelare Biazar Biazar

Name of organization / entity

Guilan University of Medical Sciences,Alzahra Hospital

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of ultrasound-guided versus fluoroscopy-guided sacroiliac joint intra-articular injection in patients with sacroiliac joint disorders

Public title
Comparison of ultrasound and fluoroscopic guided intra-articular sacroiliac injection in patients with sacroiliac joint disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years old who have been nominated for sacroiliac joint injection due to persistent sacroiliac joint pain Out of 7 tests in clinical examinations, at least 4 examinations are positive The patient's average pain over the past week is at least 3 out of 10 (in Numerical Rating scale) The patient has persistent pain for at least 6 weeks and does not respond to at least one or two conservative treatments such as oral medications, anti-inflammatory drugs, analgesics, muscle relaxants, and physical therapies.
Exclusion criteria:
Complaints of lower back pain so that the distinction between sacroiliac joint and L5 / S1 fastogenic back pain is indistinguishable. Dye contrast sensitivity Contraindications to fluoroscopy Active lesion in structures of sacroiliac joint such as lumbar spine pathologies and hip pathology Secondary orthopathy to rheumatoid causes Abnormal anatomy Infection, bleeding and trauma at the site Previous history of intro-articular injection Active inflammatory diseases Untreated coagulopathies
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Investigator

Sample size
Target sample size: **122**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals will be grouped by block randomization. First, 4 blocks will be prepared as follows: AABB, ABAB, ABBA, BBAA, BABA, BAAB These blocks are then randomly selected and individuals will be divided into two groups according to A and B: ultrasound and fluoroscopy. This will be repeated continuously.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is single-blinded ,patients and the physician performing the work are aware of the treatment for each patient and the evaluator is unaware.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street,Rasht
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Rasht
Province
Guilan
Postal code
4144654839
Approval date
2020-12-09, 1399/09/19
Ethics committee reference number
IR.GUMS.REC.1399.408

Health conditions studied

1

Description of health condition studied
Chronic pain of sacroiliac joint
ICD-10 code
M46.98
ICD-10 code description
Unspecified inflammatory spondylopathy, sacral and sacrococcygeal region

Primary outcomes

1

Description
Intensity of pain
Timepoint
Before the procedure, zero time of the procedure, 15 minutes and 24 hours after the procedure
Method of measurement
Based on the Numerical Rating Scale (a scale for pain)

2

Description
Duration of the procedure
Timepoint
At the end of procedure
Method of measurement
Measuring time based on minutes

3

Description
Complications of the procedure (hypotension,urticaria)
Timepoint
During the procedure and at the end
Method of measurement
Blood pressure measurement with mercury sphygmomanometer, patient observation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group Sacroiliac joint injection with ultrasound guide: patients will be positioned prone with a pillow under their abdomen. A low-frequency curved transducer (4 to 6 megahertz) perpendicular to the skin on the external sacrum will be placed in the midline with a cross-sectional view to detect the sacral hiatus. The probe will be moved laterally until the lateral edge of the sacrum is visible, then moved toward the caudal to find the inner direction of the iliac bone. At this location, the sacroiliac joint appears as a wedge-shaped hypoechoic structure. The suitable place for injection is at the level of the second sacral foramen, which is approximately 2-3 centimeters above the caudal surface of the sacroiliac joint. lidocaine1% (manufacturer: Caspian tamin Company. made in Iran) will be injected subcutaneously into the inner edge of the probe. A needle with a 22 gauge in-plane and oblique and anterior position will be inserted into the joint. After the needle is inserted deep into the iliac bone, it is no longer visible with an ultrasound. The popping sound is felt when the synovial joint ruptures.
Category
Treatment - Devices

2

Description
Intervention group Sacroiliac joint injection with fluoroscopic guide: Initially, standard monitoring will be performed throughout the procedure. The patient will be positioned in the prone with the head turned to one side. A pillow is placed under the abdomen to bend the waist. Under the direct anterior-posterior view, the sacroiliac joint shows several lines that point toward the craniocerebral cortex in a semi-parallel pattern. The lateral line shows the ventral or anterior margin of the joint, and the inner line represents the dorsal or posterior margin of the joint. For a better view of the lower areas of the upper posterior iliac and iliac crest, the C-arm is initially rotated 30 degrees from the caudal to the axial plate. The C-arm is angled, usually between 5 and 20 degrees in the opposite direction, until the space of the lower joint is clearly defined. The target area is located along the lower posterior part of the joint 1 to 2 centimeters towards the cephalad from the most caudal point. The target area will be prepared and draped with the usual sterile method. The skin is anesthetized with 1 to 2 cc of lidocaine 1% through needle number 25. Spinal needle Number 22 travels coaxially to the lower bridge of the sacroiliac joint and will be confirmed by giving alternating images at regular intervals (every 2 to 4 millimeters of the needle advance). When the posterior surface of the sacroiliac joint is contacted, the needle goes to the point where it ruptures the joint capsule. Resistance changes will be commonly felt as the needle passes through the capsular tissue, and the tip of the needle usually deflects slightly when it strikes the surface of the ilium.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Pain Clinic of Shafa Hospital
Full name of responsible person
Dr Cyrus Emiralavi
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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3

Recruitment center

Name of recruitment center
Pain Clinic of Velayat Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice President of Research Guilan university of medical sciences

Full name of responsible person
Dr Mohammadreza Naghipoor

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Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street,Rasht

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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
Vice President of Research Guilan 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
Rasht University of Medical Sciences

Full name of responsible person
Dr Gelareh Biazar

Position
associate professor, Anesthesiologist

Latest degree
Specialist

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Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available