

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of the intra-articular injection versus quadruple injection at the joint surface in the treatment of sacroiliac joint pain

Protocol summary

Study aim

Evaluating the efficacy and safety of two methods of intra-articular injection and 4 injections at the joint level in the recovery of sacroiliac joint pain

Design

Clinical trial with two intervention groups, with parallel groups, double-blind, phase 2 on 40 patients, randomized

Settings and conduct

The place of study is the office of the supervisors and consultants (pain fellowship and endocrinology specialist), in the first group (20 people) intra-articular injection and in the second group (20 people) peri-articular injection (4 specific points around the joint) by a specialist doctor. will be The injected drug is the same in both groups. double blind (patient and researcher). Pain level of patients according to VAS scale (before injection, one hour after injection, one month after injection). Also, side effects are determined after the intervention.

Participants/Inclusion and exclusion criteria

Admission requirements: patients (ASA (American Society of Anesthesiologists) in class I and II, 18 years old and above, referred to the Yazd city pain clinic, who came with complaints of back pain and during clinical examinations, they had a clinical diagnosis of SIJ joint pain. Exclusion conditions: history of any uncontrolled medical disease - history of rheumatological or infectious diseases (RA, brucellosis)

Intervention groups

First group: intra-articular injection The second group: injection around the joint (4 specific points around the joint) The drug injected in both groups is the same, which includes a mixture of Hexal brand triamcinolone in the amount of 40 mg plus Myungmoon brand marcaine (bupivacaine) in the amount of 0-25% with a volume of 8cc, and the injection in both groups during the operation and the injection under guidance. Radiology (C-arm) will be performed by a specialist doctor.

Main outcome variables

pain intensity based on the VAS scale and side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210725051977N3**

Registration date: **2023-01-15, 1401/10/25**

Registration timing: **prospective**

Last update: **2023-01-15, 1401/10/25**

Update count: **0**

Registration date

2023-01-15, 1401/10/25

Registrant information

Name

Masoud Khoshbin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3726 9893

Email address

masoudkhoshbin@iauyazd.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	presence of the researcher. Then 40 patients are given to the researcher to evaluate the severity of pain and complications after the injection.
Scientific title Comparison of the intra-articular injection versus quadruple injection at the joint surface in the treatment of sacroiliac joint pain	Placebo Not used
Public title Comparison of the intra-articular injection versus quadruple injection at the joint surface in the treatment of sacroiliac joint pain	Assignment Parallel
Purpose Treatment	Other design features
Inclusion/Exclusion criteria Inclusion criteria: ASA (American Society of Anesthesiologists) patients in class I and II, 18 years old and above, referred to Yazd city pain clinic, who came with complaints of back pain and during clinical examinations, they had a clinical diagnosis of SIJ joint pain. Exclusion criteria: History of any uncontrolled medical illness History of rheumatological or infectious diseases (RA, brucellosis)	Secondary Ids empty
Age From 18 years old	Ethics committees
Gender Both	1
Phase 2	Ethics committee
Groups that have been masked • Participant • Investigator	Name of ethics committee Ethics Committee of Yazd Islamic Azad University Medical School
Sample size Target sample size: 40	Street address Safaieh, Alam Square, Boulevard of the Shohadaie Gomnam, Ali Ibn Abitaleb Medical School
Randomization (investigator's opinion) Randomized	City Yazd
Randomization description The sample size of the study is 40 patients. The first patient who admitted to the office and meets the inclusion criteria will be No. 1 and the 40th patient will be No. 40. In advance, using the https://www.random.org , from the "List Randomizer" section of the website, the numbers 1 to 40 is randomly divided into two groups of 20 (the first twenty patients for the intra-articular injection group and the second 20 patients for the periarticular injection group). Example: Number 5 is in the intra-articular injection group in randomization of numbers 1 to 40, therefore, the fifth patient who meets the inclusion criteria will be in the intra-articular injection group.	Province Yazd
Blinding (investigator's opinion) Double blinded	Postal code 8915813135
Blinding description The researcher and the patient are unaware of the grouping and what type of injection method (intra-joint or peri-joint) was performed. in such a way that the specialist doctor randomly selects each patient's group and Using the random numbers obtained from the List Randomizer website https://www.random.org , before referring to the operating room, he determines and performs the injection in the operating room without the	Approval date 2022-12-14, 1401/09/23
	Ethics committee reference number IR.IAU.YAZD.REC.1401.062
	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 intensity
	Timepoint Pain intensity of the patient at the beginning of the study (before the start of the intervention), one hour after the injection and 4 weeks after the injection
	Method of measurement Visual Analogue Scale (VAS)
	Secondary outcomes

1

Description

Frequency of side effects in each group

Timepoint

one hour after the injection and 4 weeks after the injection

Method of measurement

check list including possible adverse (including injection site infection, pain aggravation, etc.)

Intervention groups

1

Description

Intervention group: Intra-articular injection Triamcinolone mixture of Hexal brand in the amount of 40 mgPlusMarcaine (bupivacaine) of Myungmoon brand is 0-25% with a volume of 8cc.

Category

Treatment - Drugs

2

Description

Intervention group: Intraoperative injection around the joint (4 specific points around the joint) Triamcinolone mixture of Hexal brand in the amount of 40 mgPlusMarcaine (bupivacaine) of Myungmoon brand is 0-25% with a volume of 8cc.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Personal office of Dr Masoud Khoshbin - Pain fellow

Full name of responsible person

Dr Masoud Khoshbin

Street address

40th dead end, in front of Sepah, Shahid Sadoughi Boulevard, Yazd- Iran

City

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Province

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Email

masoudkhoshbin@iauyazd.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Ahmad Shajari

Street address

Safaieh, Alam Square, Ali Ibn Abitaleb Medical School

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Phone

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Dr Masoud Khoshbin

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Yazd, Shahid Sadoughi Boulevard, in front of Sepah, 40th dead end

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Masoud Khoshbin

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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