Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Study the effect of Ultrasound-Guided Sacroiliac joint single dose platelet-rich plasma injection in patients with sacroiliac joint pain. A, single-arm, before and after, open-label clinical trial

Protocol summary

Study aim

To determine the effect of platelet-rich plasma injection under ultrasound guidance on pain intensity and functional improvement in patients with sacroiliac joint pain.

Design

It is a Phase 2, single-arm clinical trial in which a single dose of platelet-rich plasma is injected into the sacroiliac joint under ultrasound guidance in 26 patients with sacroiliac joint pain.

Settings and conduct

This study is conducted in the pain clinics of Imam Khomeini Hospital in Tehran, on patients with sacroiliac joint pain. Provocative tests and MRI are performed for the absence of the joint inflammation. If three tests are positive and MRI is normal, sacroiliac joint disorder is diagnosed. Patients with chronic pain and NRS above 5 who have not responded to drug treatments are enrolled. To prepare PRP, blood is taken from the cubital vein and CPD-A1 is added. Two centrifugations are performed to concentrate the platelets. All procedures are performed in the operating room under proper monitoring. The patient is placed in a suitable position and 10 cc of peri-articular PRP is injected. Patients are evaluated one and three months later in terms of pain intensity (NRS) and function (ODI)

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 20-60 with sacroiliac joint pain, NRS >5 in the last 3 months, based on clinical exams and positive results from 3 provocative tests. Exclusion Criteria: Thrombocytopenia, local infection at injection site, NSAIDs within 48 hours before injection, systemic corticosteroids within 1 month before injection, malignancy, pregnancy, rheumatological diseases, uncontrolled hormonal disorders, systemic inflammatory diseases, neurological/psychological disorders, midline pain above L5 level.

Intervention groups

platelet-rich plasma injection

Main outcome variables

Pain Intensity: Measured using the NRS Functional Improvement: Evaluated using the ODI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141023019640N4**
Registration date: **2024-09-01, 1403/06/11**
Registration timing: **prospective**

Last update: **2024-09-01, 1403/06/11**
Update count: **0**

Registration date

2024-09-01, 1403/06/11

Registrant information

Name

Hossein Majedi Ardakani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2234 4084

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hmajedi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-18, 1403/06/28

Expected recruitment end date

2025-04-21, 1404/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of Ultrasound-Guided Sacroiliac joint single dose platelet-rich plasma injection in patients with sacroiliac joint pain. A, single-arm, before and after, open-label clinical trial

Public title

Study the effect of Ultrasound-Guided Sacroiliac joint single dose platelet-rich plasma injection in patients with sacroiliac joint pain. A, single-arm, before and after, open-label clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 20-60 years with sacroiliac joint pain and an NRS (Numeric Rating Scale) score greater than 5 during the last three months, based on clinical examinations and positive results of three sacroiliac joint provocative tests (Faber, Gaenslen, iliac compression, Fortin Finger, Yeoman, thigh thrust, iliac distraction), will be included in the study.

Exclusion criteria:

Thrombocytopenia (platelets less than 150,000 per microliter), local infection at the injection site, use of non-steroidal anti-inflammatory drugs within 48 hours before injection, use of systemic corticosteroids within a month before injection, malignancy, pregnancy, rheumatological diseases, Uncontrolled hormonal disorders, systemic inflammatory diseases, neurological or psychological disorders, age less than 20 years or more than 60 years, patients with midline pain above the level of the fifth lumbar vertebra.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **26**

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 Tehran University of Medical Sciences

Street address

Pain research Center, Neuroscience Institute, Imam Khomeini Hospital Complex, Dr. Gharib street

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2023-08-03, 1402/05/12

Ethics committee reference number

IR.TUMS.NI.REC.1402.060

Health conditions studied

1

Description of health condition studied

Sacroiliac joint pain

ICD-10 code

G89.2

ICD-10 code description

Chronic pain, not elsewhere classified

Primary outcomes

1

Description

Pain Intensity

Timepoint

The patient's pain intensity is measured before the intervention and at one and three months after the intervention (PRP injection into the sacroiliac joint).

Method of measurement

Numeric Rating Scale (NRS)

Secondary outcomes

1

Description

Functionality

Timepoint

The patient's functional improvement is measured before the intervention and at one and three months after the intervention (PRP injection into the sacroiliac joint)

Method of measurement

Oswestry Disability Index (ODI)

Intervention groups

1

Description
Intervention group: PRP injection (Royagen kits, made by Aria Mobna Diagnos Company) is performed as a single dose with a volume of 10 cc.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Pain clinics of Imam Khomeini Hospital in Tehran
Full name of responsible person
Dr. Hossein Majedi Ardakani
Street address
Pain research center, neurosciences institute ,Imam Khomeini Hospital Complex , Dr. Gharib Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ali Akbari Sari
Street address
Keshavarz Blvd., corner of Qods St., Central Organization of the University, 6th floor of Research and Technology Vice-Chancellor
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Hossein Majedi Ardakani
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available