Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study the effect of Platelet-Rich Plasma (PRP) in treatment of patients with lumbar discogenic pain

Protocol summary

Study aim
The effect of PRP in the treatment of patients with chronic pain caused by based discopathy
Design
Clinical trial with control group, Non-random, with parallel groups, one-way blind, phase 2 on 40 patients.
Settings and conduct
In the field of disc-related pain, Bahonar Hospital of Kerman, patients after dividing into two groups will have both the same treatment methods and only in the second group PRP will be placed in disk space at the end of treatment. People who check the rate of pain changes and MRI, as well as the person who analyzes the results, will not be aware of how people divided into groups.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged between 20 and 60 years; Patients with chronic low back pain caused by discopathy for more than 6 months; Failure in common medical treatments used; Damaged disc, annular rupture or disc removed on radiography; The patient's disc should be one level Exclusion criteria: Existence of bleeding disorder; Pregnancy; Local or systemic infection; Existence of a medical or psychological condition; Drug use
Intervention groups
The first group will receive routine treatment without PRP. The second group will receive routine treatment with PRP.
Main outcome variables
Change in pain; Change in MRI

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210128050164N1**
Registration date: **2021-02-18, 1399/11/30**
Registration timing: **prospective**
Last update: **2021-02-18, 1399/11/30**
Update count: **0**
Registration date
2021-02-18, 1399/11/30

Registrant information
Name
Vahid Tavakolian Ferdousie
Name of organization / entity
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Iran (Islamic Republic of)
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+98 35 3272 2658
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-02-19, 1399/12/01
Expected recruitment end date
2021-04-21, 1400/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study the effect of Platelet-Rich Plasma (PRP) in treatment of patients with lumbar discogenic pain

Public title
Effect of platelet-rich plasma on discopathic pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged between 20 and 60 years Patients with

chronic low back pain caused by discopathy for more than 6 months Failure in commonly used medical treatments Damaged disc, annular rupture, or disc removed on radiograph The patient disk should be one level.

Exclusion criteria:

Existence of bleeding disorder Pregnancy Local or systemic infection Existence of a medical or psychological condition Narcotics Use

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

A person who monitors the amount of pain and disc changes on MRI will not know which group the person is in. Also, the person who analyzes the information will not know which group the people are in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman, the beginning of Haft Bagh Alavi Blvd, campus of University of Medical Sciences

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2021-01-19, 1399/10/30

Ethics committee reference number

IR.KMU.REC.1399.583

Health conditions studied

1

Description of health condition studied

lumbar discogenic pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

1 day, 1 week, 1 month, 6 months, 12 months, 18 months and 24 months after intervention

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Disc changes on MRI

Timepoint

Three months before surgery,12 months and 24 months after intervention

Method of measurement

Pfirrmann scoring system

Intervention groups

1

Description

Intervention group: After the test description and written consent from the patient, about 20 cc of blood on ACD anticoagulant will be taken from the patient and immediately transferred to the laboratory. In the laboratory, a blood sample will be centrifuged and platelet-rich plasma (PRP) will be separated and prepared and given to a physician for injection.

Category

Treatment - Drugs

2

Description

Control group: In this group, only routine treatments will be performed and there will be no additional treatment or medication.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Bahonar Hospital

Full name of responsible person
Mehdi Ahmadi Nejad

Street address
Qarni St. - Shahid Bahonar Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Abbas Pardakhti

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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
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Vahid Tavakolian ferdousie

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Neurosurgery

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Person responsible for scientific inquiries

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Full name of responsible person
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Assistant Professor

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Specialist

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Person responsible for updating data

Contact

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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

Age, gender, PRP preparation method, surgery method

When the data will become available and for how long

Access period starts one year after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

To do this on more people or to use stem cells using this research

From where data/document is obtainable

Dr. Mohsen Shahba; msneurosurgeon@gmail.com; 00989134419232

What processes are involved for a request to access data/document

It takes a month for documents or data files to reach the individual.

Comments