

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 35 3272 2658

Email address

tavakolian.v@gmail.com

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

Pfirsch 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

City

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7613747181

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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

Street address

Kerman University of Medical Sciences, Medical
University Campus, Haft-Bagh Highway, Kerman, Iran

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vcr@kmu.ac.ir

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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Kerman University of Medical Sciences, Medical
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mohsen Shahba

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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msneurosurgern@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

vahid Tavakolian Ferdousie

Position

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Latest degree

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Other areas of specialty/work

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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