Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the effectiveness of autologous PRP in postrolateral arthrodesis of lumbar spine surgery

Protocol summary

Study aim
Efficacy of autologous platelet-rich plasma in arthrodesis after lumbar spine posterior stabilization surgery

Design
Two arm parallel group non randomised control trial, double-blind, phase 3 on 20 patients.

Settings and conduct
20 patients who are candidates for lumbar spine stabilization surgery referred to Rasoul Akram Hospital, on the day of operation, venous blood is taken from the patient in a special tube to prepare Platelet Rich Plasma (PRP) and transferred to the laboratory. PRP is prepared in the laboratory by the double spin method. Then, at the end of the operation, 2 cc of PRP per vertebra along with the allograft bone in the posterolateral space on the right or left side of the vertebral column and then the combination of 2cc of normal saline serum per each vertebra along with the allograft bone in the posterolateral space on the opposite side Placed. Then, the patient is followed up with CT scan images in the third, sixth, and twelfth months after the operation, and bone formation is evaluated by two radiologists who are unaware of the intervention site.

Participants/Inclusion and exclusion criteria
inclusion criteria: patients in the age range of 16 to 69 years who are candidates for posterior stabilization surgery of the lumbar spine. Exclusion criteria: Patients who have malignancy, blood diseases and osteoporosis, or have a history of spine surgery.

Intervention groups
Intervention group: Platelet-rich plasma is placed in combination with allograft bone in the posterolateral space on the right or left side of the patient's vertebral column. Control group: On the opposite side of the intervention group (right or left), the combination of allograft bone with normal saline (placebo) is placed in the posterolateral space of the patient's vertebral column..

Main outcome variables
arthrodesis rate in CT scan images

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171124037606N4**
Registration date: **2023-05-08, 1402/02/18**
Registration timing: **retrospective**

Last update: **2023-05-08, 1402/02/18**
Update count: **0**

Registration date
2023-05-08, 1402/02/18

Registrant information

Name
Alireza Tabibkhooei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6435 2228

Email address
tabibkhooei.a@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-01, 1400/07/09

Expected recruitment end date
2022-12-24, 1401/10/03

Actual recruitment start date
2021-10-01, 1400/07/09

Actual recruitment end date
2022-12-24, 1401/10/03

Trial completion date

2022-12-24, 1401/10/03

Scientific title
Comparing the effectiveness of autologous PRP in postrolateral arthrodesis of lumbar spine surgery

Public title
The effect of autologous platelet-rich plasma on spinal arthrodesis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with lumbar spine fracture Patients with lumbar canal stenosis Patients with lumbar spondylolisthesis
Exclusion criteria:
Patients with a history of spine surgery Patients suspected of local infection of the spine Patients with canal stenosis or fractures of cervical and thoracic vertebrae Patients with malignancy Patients treated with immunosuppressive drugs Patients with platelet disorders Patients with severe osteoporosis

Age
From **16 years** old to **69 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
One side of the patient's lumbar spine (right or left) is used as an intervention sample and the other side of the patient's spine is used as a control sample.
Actual sample size reached: **20**
More than 1 sample in each individual
Actual sample size in each individual: **2**
One side of the patient's lumbar spine (right or left) is used as an intervention sample and the other side of the patient's spine is used as a control sample.

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The outcome evaluators, who are two radiologists, entered their evaluations in separate questionnaires and numerically, and considering that the interventional material is not visible in the imaging, in relation to which side of the patient's spine (right or left) They are completely unaware of the intervention. The data analyst, who is a statistician, also receives the data numerically and is unaware of which side of the patient's spine (right or left) the intervention took place.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535

Approval date
2021-09-26, 1400/07/04

Ethics committee reference number
IR.IUMS.FMD.REC.1400.492

Health conditions studied

1

Description of health condition studied
Postrolateral arthrodesis after lumbar spine fixation

ICD-10 code
M96.0

ICD-10 code description
Pseudarthrosis after fusion or arthrodesis

Primary outcomes

1

Description
Arthrodesis rate based on Hounsfield index in CT scan images

Timepoint
Evaluation of posterolateral arthrodesis in the third, sixth and twelfth months after surgery

Method of measurement
Helical 16-slice CT scan machine

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: On the day of surgery, 26 cc of venous blood was taken from the patient under sterile conditions and placed in 3 special tubes for the preparation of platelet-rich plasma (manufactured by Becton Dickinson) containing 1.5 cc of Acid Citrate Dextrose (ACD) with a volume of 8.5 cc. are poured and transferred to the laboratory. In the laboratory, platelet-rich plasma is prepared by the double spin method, in this way, first all 3 tubes are placed in a centrifuge (Pars Azma model SH.13) with 1600 rpm for 12 minutes and after finishing the layer work The plasma is separated under sterile conditions and enters the test tube without anticoagulant. Then it is placed again in the centrifuge with 2700 rpm for 5 minutes. After finishing the work, the upper two-thirds of the plasma is separated from the tube and the remaining one-third is gently shaken in a pendulum after a 5-minute rest so that the concentrated platelets merge with the plasma. Then the platelet-rich plasma was transferred to the operating room and at the end of the operation, 2 cc per vertebra in combination with allograft bone (manufactured by Ceno Bone Company) in the posterolateral space on the right or left side of the vertebral column and then the combination of allograft bone with 2 CC of normal saline serum is placed for each vertebra in the posterolateral space on the opposite side of the vertebral column. Then, the patient was followed up for one year with CT scan imaging in the third, sixth and twelfth months after the operation, and the amount of arthrodesis based on the Hounsfield index was numerically calculated in separate questionnaires by two radiologists who did not know about the side of the intervention. will be recorded. Then the average of the reported numbers is delivered to the statistician for statistical calculations.

Category

Treatment - Drugs

2

Description

Control group: the posterolateral space of the vertebral column on the opposite side in the patients of the intervention group, where the combination of 2 cc of normal saline serum is placed for each vertebra along with the bone graft. Then, the patient was followed up for one year with CT scan imaging in the third, sixth and twelfth months after the operation, and the amount of arthrodesis based on the Hounsfield index was numerically calculated in separate questionnaires by two radiologists who did not know about the side of the intervention. will be recorded. Then the average of the reported numbers is delivered to the statistician for statistical calculations.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Rasoul Akram hospital

Full name of responsible person
Alireza Tabibkhooei

Street address
Hazrate Rasool hospital, Niyayesh street, Sattarkhan

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6435 2190

Email
hrmc@iums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Hosein Keyvani

Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 8670 2503

Email
research@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Alireza Tabibkhooei
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Rasool Akram Hospital, Niyayesh Avenue, Sattarkhan Avenue
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 2228
Fax
Email
tabibkhooei.a@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Alireza Tabibkhooei
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Rasool Akram Hospital, Niyayesh Avenue, Sattarkhan Avenue
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 2228
Fax
Email
tabibkhooei.a@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Alireza Tabibkhooei
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Rasool Akram Hospital, Niyayesh Avenue, Sattarkhan Avenue
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 2228
Fax
Email
tabibkhooei.a@iums.ac.ir

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
After de-identifying people, the information about the main outcome will be accessible
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
For research purposes, descriptive raw data is made available at the discretion of the University Research Committee
From where data/document is obtainable
by Email: tabibkhooei.a@iums.ac.ir
What processes are involved for a request to access data/document
After receiving the email about making the information available after checking the qualification of the researcher by the research committee, the information will be sent to the academic email address of the person within a week.

Comments