Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the therapeutic effects of using peripheral blood stem cells in spinal fusion in patients with thoracolumbar fractures

Protocol summary

Study aim

Study of the therapeutic effect of using stem cells derived from peripheral blood in spinal fusion in patients with thoracolumbar fractures And comparing it with conventional therapy without using stem cells

Design

The 30 patients are placed in parallel in two groups of 15.

Settings and conduct

In the operating room of the Neurosurgery Department of Shahid Kamyab Hospital, Mashhad, the intervention group using stem cells and surgical operation of the spinal column are subjected to posterior instrumentation and fusion with allograft , and the control group undergoes only a posterior column instrumentation And fusion with the allograft. method:First, patients are checked for serum hemoglobin levels then under sterile venous blood conditions in triple blood bags Contains 63ml CPD-A.Then 500 ml of normal saline is injected 0.9% to the patient and 6 hours after sampling, hemoglobin is rechecked . Then the centrifuge stem cells were extracted from the peripheral blood through two centrifuges and used during the operation with allograft bone.A 0.5 cc sample is sent for flow cytometry

Participants/Inclusion and exclusion criteria

Conditions of entry: 1- The age of the patient is between 20-60 years; 2- The patient's level of consciousness when admitted 2-15 ; 3. The need for spine surgery. Exit Conditions: 1. Has specific diseases such as HIV +, HBV +, HCV + 2- Pregnancy 3- Probability of patient not following 4. Having previous bone malignancy 5. Pelvic fracture 6-Background illnesses including osteoporosis 7. Use steroid

Intervention groups

intervention group: Patients with thoracolumbar fractures undergoing spinal surgery along with the use of stem cells at the time of surgery Control group: Patients with thoracolumbar fracture that undergo the usual surgical procedure

Main outcome variables

Evaluation of bone fracture fusion of spinal CT scan with fine cats based on Glassman grading

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100407003647N2**
Registration date: **2019-10-13, 1398/07/21**
Registration timing: **retrospective**

Last update: **2019-10-13, 1398/07/21**
Update count: **0**

Registration date

2019-10-13, 1398/07/21

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

8592180 0511

Email address

ehsaeemr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-19, 1396/06/28

Expected recruitment end date

2018-05-30, 1397/03/09

Actual recruitment start date

2017-09-19, 1396/06/28

Actual recruitment end date

2018-05-30, 1397/03/09

Trial completion date
2019-05-15, 1398/02/25

Scientific title
Evaluation of the therapeutic effects of using peripheral blood stem cells in spinal fusion in patients with thoracolumbar fractures

Public title
treatment effect of peripheral blood stem cells in repair of fractures
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age 20-60 years GCS:12-15 spine surgery is needed
Exclusion criteria:
HIV+,HBV+,HCV+ pregnancy Probability of patient not following Previous bone malignancy Pelvic fracture Background illnesses including osteoporosis Taking steroids
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
research ethice certificate school of medicin-mashhad university of medical science
Street address
fadaeeian eslam
City
mashhad
Province
Razavi Khorasan
Postal code
9166637477
Approval date
2017-03-11, 1395/12/21
Ethics committee reference number
IR.MUMS.REC.1395.633

Health conditions studied

1

Description of health condition studied
thoracolumbar fracture fusion
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Evaluation of bone fracture fusion of spinal CT scan with fine cats based on Glassman grading
Timepoint
12 months after spinal surgery
Method of measurement
Interpretation of CT scan with subtle cats of the spine performed by the surgeon

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Uses of Mesenchymal cell derived from peripheral blood
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
shahid kamyab Hospital
Full name of responsible person
mohammad reza ehsaee
Street address
fadaeeian eslam
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Province
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Postal code
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+98 51 3802 6441
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
mohsen tafaghodi
Street address
daneshgah street
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Province
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9138813944
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+98 51 3843 9070
Email
TafaghodiM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
mohammadreza ehsaee
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
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Person responsible for updating data

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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
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