

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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

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Email

ehsaeemr@mums.ac.ir

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

City

mashhad

Province

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Postal code

9138813944

Phone

+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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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