

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Studying the effect of bone marrow mesenchymal stem cell injection into the subarachnoid space on improvement and reduction of complications in spinal cord injured patients

Protocol summary

Summary

Main outcome: The safety and effect of mesenchymal stem cell therapy on spinal cord injured patients will be assessed. Design: 30 patients with spinal cord injury will be selected and will be divided randomly into two groups. Around 10 million cells (three times) will be injected; MRI and physical assessments before and after cell therapy will be done by a physician who does not know the groups. Setting and conduct: Cells will be isolated from bone marrow of patient under aseptic conditions; cells will be culture in DMEM high glucose until proliferation and the mesenchymal stem cell type will be identified by immunostaining. After collection of enough mesenchymal stem cells they will be injected in to the patient's subarachnoid space. Participants, including major eligibility criteria: Patients must have 13-60 years old, patients must not have fever, convulsion and meningitis and any other infectious disease, the health condition of the patients must be stable, patients must have self control on breath, by occurrence of any side effect such as fever, convulsion or tumor that patient will be excluded from study. Interventions: Patients will have one bone marrow puncture and three subarachnoid injections of stem cells (10million/each). Variables: Main variables are: improvement in sense and motor function, MRI of injury size and type, physical examinations results, effect of each injection on improvement , effect of age on improvement, control on urination and defecation, tumor formation, fever and convulsion and any other complication or side effect occurrence will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013050813267N1**

Registration date: **2014-02-06, 1392/11/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-02-06, 1392/11/17

Registrant information

Name

Farshad Homayouni Moghadam

Name of organization / entity

Royan Institute for Biotechnology

Country

Iran (Islamic Republic of)

Phone

Email address

f_homayounim@yahoo.com

Recruitment status

Recruitment complete

Funding source

Ali-Ebne Abitaleb Faculty of Medicine, Islamic Azad University, Yazd Branch

Expected recruitment start date

2016-12-05, 1395/09/15

Expected recruitment end date

2017-11-01, 1396/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of bone marrow mesenchymal stem cell injection into the subarachnoid space on

improvement and reduction of complications in spinal cord injured patients

Public title

Studying the effect of bone marrow mesenchymal stem cell injection into the subarachnoid space on improvement and reduction of complications in spinal cord injured patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: filling the questionnaire by patient and his/her family; age 13-60; no more than 3 months passed from injury date, no history of cancer in patient and his family; no history to other chronic disorder; no other acute disease at present; self control on breathing; no contribution in the other studies; no convulsion and fever; no infectious diseases in patient like AIDS and hepatitis, and meningitis. Exclusion criteria: patient request; occurrence of fever and convulsion after cell therapy, occurrence of any other complication; infection, instability of patient's health conditions ; worsening of the patient's disease.

Age

From **13 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iranian Ministry Of Health Ethic Committee

Street address

Tehran, Azady Boulevard

City

Tehran

Postal code

Approval date

2013-03-14, 1391/12/24

Ethics committee reference number

1- k91p/69

Health conditions studied

1

Description of health condition studied

Spinal Cord Injury

ICD-10 code

T09.3

ICD-10 code description

Injury Of Spinal Cord, Level Unspecified

Primary outcomes

1

Description

Evaluation of Generation of Ectopic Tissue Such as Tumor After Stem Cell Therapy

Timepoint

Three months after third injection

Method of measurement

MRI; Physical Examination; Biochemical Tests About Presence of Ectopic Tissue or Tumor in Patients

Secondary outcomes

1

Description

Improvement In Somatic Sensation And Control Of Bladder , And Motor Function Improvements

Timepoint

1 Month

Method of measurement

Physical Examination

Intervention groups

1

Description

In intervention group, at first bone marrow aspiration (10ml) will be done and mesenchymal stem cells will be collected using centrifuge and Ficoll solvent. Cells will be cultured and after proliferation they will be collected by trypsinization and microbial, quality and quantity analysis will be done on them. Collected cells with the quantity of 10-20 million cells will be solved in 5ml distilled water, and will be injected slowly (5 minutes) to sub arachnoid space of patient using lumbar puncture technique by anesthesiologist in operating room and in sterile conditions. Each patients will have 3 injections with near to 1 month interval between them.

Category

Treatment - Surgery

2

Description

In control group just vehicle of cells (distilled water) with the same volume of intervention group (5ml) will be injected to the sub arachnoid space of patients. Injecting solvent will be injected slowly (5 minutes) and by anesthesiologist in the operating room and in sterile conditions. Each patient in this group will receive 3 injections by one month interval between them. Bone Marrow aspiration will not perform in this group but just the action of bone marrow aspiration will be simulated in the operating room for them.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Yazd University Of Medical Sciences, Neurobiomedical Research Center

Full name of responsible person

Farshad Homayouni Moghadam, Hamid Hobobati

Street address

Yazd, Shohadaye Gomnam Boulevard, Shahid Sadoughi Yazd University of Medical Sciences, Neurobiomedical Research Center

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Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi Yazd University Of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Dr Fatemeh Ezodini

Street address

Shahid Sadoughi Yazd University Of Medical Sciences, Vice Chancellor for Research, Bahonar Street

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi Yazd University Of Medical Sciences, Vice Chancellor for Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Sadoughi Yazd University Of Medical Sciences, Yazd, Iran

Full name of responsible person

Hamid Hobobati

Position

Neurosurgeon

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

PhD of Physiology, Stem Cell Researcher

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty