

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of Intrathecal Transplantation of Autologous Schwann Cell and Bone Marrow Mesenchymal Stromal Cell on Urodynamic Parameters in Patients With Complete Spinal Cord Injury: Results From a Randomized Open-Label Phase 1/2

Protocol summary

Study aim

Assessing the effect of intrathecal transplantation of combination of autologous Schwann cell and bone marrow mesenchymal stromal cell on urodynamic parameters in patients with complete spinal cord injury

Design

This study is a randomized, controlled, and open-label phase 1/2 trial on 32 patients.

Settings and conduct

This study includes 32 patients undergoing transplantation of a combination of autologous Schwann cell and bone marrow mesenchymal stem cell. Patients will be assessed in terms of the study outcomes before and 6 months after treatment

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 60 Root lesion less than three level Complete spinal cord injury (class A in ASIA scale) The patient who fills informed consent
Exclusion criteria: Systemic diseases like diabetes, Cancer, Advanced neuropathy, Myopathy, Neuromuscular disorder, etc. Epilepsy Concurrent lesions of peripheral nerve including traumatic lesion Brain damage

Intervention groups

Intervention group: In this group, patients' stem cells were isolated by bone marrow aspiration and Schwann cells by removing part of the sural nerve and after culturing and preparing the cells, at a concentration of one million cells per milliliter through Lumbar punctures are transplanted. Control group: Patients with complete spinal cord injury who were evaluated without intervention during the follow-up period.

Main outcome variables

Primary outcomes: Bladder Maximum Capacity, Maximum Pressure of Detrusor in Filling, Maximum Pressure of Detrusor in Voiding. Secondary outcomes:

Quality of Life

General information

Reason for update

Natural urological changes in spinal cord injury patients over time will be a factor in the bias in the study results. Due to the nature of phase one and two of the article and the purpose of investigating the possible effectiveness of the intervention and creating reliable data for larger studies, including phase 3 trials, adding a control group to the intervention was necessary and important. The patients in this study were randomly assigned with a sealed envelopes from the date of the first patient's enrollment, and the trial status was changed from non-randomized to randomized. The term of "pilot study" was removed from the title.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200502047277N4**
Registration date: **2020-10-19, 1399/07/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-13, 1401/11/24**

Update count: **2**

Registration date

2020-10-19, 1399/07/28

Registrant information

Name

saeed oraei yazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 25719

Email address

Recruitment status**Recruitment complete****Funding source****Expected recruitment start date**

2020-07-01, 1399/04/11

Expected recruitment end date

2022-05-01, 1401/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Intrathecal Transplantation of Autologous Schwann Cell and Bone Marrow Mesenchymal Stromal Cell on Urodynamic Parameters in Patients With Complete Spinal Cord Injury: Results From a Randomized Open-Label Phase 1/2

Public title

The effect of combination therapy with mesenchymal stem cells and Schwann cells on urological parameters in patients with complete spinal cord injury

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 and 60 Root lesion less than three level Complete spinal cord injury (class A in ASIA scale) The patient who fills informed consent

Exclusion criteria:

Systemic diseases like diabetes, Cancer, Advanced neuropathy, Myopathy, Neuromuscular disorder, etc. Epilepsy Concurrent lesions of peripheral nerve including traumatic lesion Brain damage

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

1-2

Groups that have been masked*No information***Sample size**Target sample size: **32****Randomization (investigator's opinion)**

Randomized

Randomization description

Study subjects are divided into two equal groups by block randomization. The tool of randomization was sealed envelopes.

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**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences ,Shahid Arabi St., Yemen St., Shahid Chamran Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-06-30, 1399/04/10

Ethics committee reference number

IR.SBMU.MSP.REC.1399.153

Health conditions studied**1****Description of health condition studied**

Complete spinal cord injuries

ICD-10 code

T09.3

ICD-10 code description

Injury of spinal cord, level unspecified

Primary outcomes**1****Description**

Bladder Maximum Capacity

Timepoint

Before and 6 months after treatment

Method of measurement

Urodynamic study

2**Description**

Maximum Pressure of Detrusor in Filling

Timepoint

Before and 6 months after treatment

Method of measurement

Urodynamic study

3

Description

Maximum Pressure of Detrusor in Voiding

Timepoint

Before and 6 months after treatment

Method of measurement

Urodynamic study

4

Description

Bladder Compliance

Timepoint

Before and 6 months after treatment

Method of measurement

Urodynamic study

Secondary outcomes

1

Description

Quality of Life

Timepoint

Before and 6 months after treatment

Method of measurement

Incontinence quality of life questionnaire

Intervention groups

1

Description

Intervention group: In this group, patients' stem cells were isolated by bone marrow aspiration and Schwann cells by removing part of the sural nerve and after culturing and preparing the cells, at a concentration of one million cells per milliliter through Lumbar punctures are transplanted.

Category

Treatment - Other

2

Description

Control group: Patients with complete spinal cord injury will be evaluated according the follow up period without intervention

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shohadaye Tajrish Hospital

Full name of responsible person

Saeed Oraee Yazdani

Street address

Shohadaye Tajrish hospital, Tajrish Square.

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1989934148

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Saeed_o_yazdani@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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Intl_office@sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeed Oraee Yazdani

Position

Assistant professor

Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Details of statistical analysis results will be provided to applicants only

When the data will become available and for how long

starting 12 months after publication

To whom data/document is available

Principal investigator of other clinical trial.

Under which criteria data/document could be used

Only the results of statistical data analysis are allowed and raw data is not available to other researchers.

From where data/document is obtainable

Requests must be made via email
saeed_o_yazdani@SBMU.ac.ir.

What processes are involved for a request to access data/document

The applicant must send the reason for his request and resume to the email saeed_o_yazdani@SBMU.ac.ir. After review by the principal researcher, the data will be provided to the applicant at its discretion.

Comments