

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Safety assessment for co-transplantation of autologous olfactory ensheathing cells and mesenchymal stem cells in complete human spinal cord injury

Protocol summary

Study aim

Safety assessment for co-transplantation of autologous olfactory ensheathing cells and mesenchymal stem cells in complete human spinal cord injury

Design

A non-randomized open-labeled controlled trial with a sample size of 10, based on 5 patients in the main intervention group (cell transplantation) and another 5 patients with similar characteristics as control (without intervention)

Settings and conduct

Patient recruitment, mucosal biopsy, and bone marrow aspiration are performed in Shohada Tajrish Hospital. Olfactory Ensheathing Cells (OECs) and Mesenchymal Stem Cells (MSCs) isolation, characterization, and culture for transplantation are done in clean room. The injection of both types of cells prepared for spinal cord injury is also done by a neurosurgeon at Shohada's Tajrish Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Traumatic thoracic spinal cord injury 2-Complete loss of sensory and motor function below the injury (ASIA Category A) 3-Time from injury at least 6 months 4-No mental disturbances in patient 5-Good patient motivation and cooperation and confirmation of written informed consent Exclusion criteria: 1-Coexisting lesion of the nervous system 2-Transection lesions of the spinal cord due to sharp objects 3-Spinal stenosis in parts other than the damaged area 4-Muscle atrophy or joint ossification 5-Severe systemic disease such as neoplasm and diabetes 6-Chronic sinusitis, tumors or polyps of nasal cavities and presented hyposmia which can prevent from mucosal biopsy

Intervention groups

1-Main group: Co-transplantation of autologous Olfactory Ensheathing Cells and Mesenchymal Stem Cells into lesioned area of spinal cord 2-Control group: Without

intervention

Main outcome variables

Type and amount of observed side effects due to the co-transplantation of autologous olfactory ensheathing cells and mesenchymal stem cells

General information

Reason for update

the lack of a sufficient number of patients with the specified age range and the opinion of the neurologist on the safety of performing this procedure on chronic patients due to their stable condition

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025930N2**

Registration date: **2018-09-29, 1397/07/07**

Registration timing: **prospective**

Last update: **2020-08-06, 1399/05/16**

Update count: **2**

Registration date

2018-09-29, 1397/07/07

Registrant information

Name

Masoud Soleimani

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-06, 1397/07/14

Expected recruitment end date

2019-03-05, 1397/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety assessment for co-transplantation of autologous olfactory ensheathing cells and mesenchymal stem cells in complete human spinal cord injury

Public title

Safety investigation of simultaneous injection of olfactory ensheathing cells and mesenchymal stem cells in treatment of spinal cord injury

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Traumatic thoracic spinal cord injury Complete loss of sensory and motor function below the injury (ASIA Category A) Time from injury at least 6 months (chronic phase) No mental disturbances in patient Good patient motivation and cooperation and confirmation of written informed consent

Exclusion criteria:

Coexisting lesion of the nervous system Transection lesions of the spinal cord due to sharp objects Spinal stenosis in parts other than the damaged area Muscle atrophy or joint ossification Severe systemic disease such as neoplasm and diabetes Chronic sinusitis, tumors or polyps of nasal cavities and presented hyposmia which can prevent from mucosal biopsy

AgeFrom **18 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **10****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

10 enrolled patients of the study are divided into two groups: the main treatment group is transplanted with

autologous olfactory ensheathing cells and mesenchymal stem cells and there is no cell therapy intervention in the control group.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Jalal AleAhmad Highway

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Postal code

1411713116

Approval date

2018-03-17, 1396/12/26

Ethics committee reference number

IR.TMU.REC.1396.737

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

Spinal Cord Injury

ICD-10 code

G95.20

ICD-10 code description

Unspecified cord compression

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

Type and amount of observed side effects due to the co-transplantation of autologous olfactory ensheathing cells and mesenchymal stem cells in patients with complete spinal cord injury in order to safety assessment for this intervention.

Timepoint

1, 6, and 12 months post cell transplantation

Method of measurement

1-General physical assessments and laboratory tests like blood, serum, and urine analysis 2- Spinal radiological assessments with MRI imaging

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with complete spinal cord injury who are co-transplanted with autologous Olfactory Ensheathing Cells (OECs) (isolated from olfactory mucosa) and Mesenchymal Stem Cells (MSCs) (isolated from bone marrow aspirate) which is injected into lesioned spinal cord in a ratio of 50:50 and cell dose of about 20-30 million.

Category

Treatment - Other

2

Description

Control group: Patients with complete spinal cord injury who are under routine cares and no extra action is performed on them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Dr.Saeed Oraee Yazdani

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Shohada Tajrish Hospital,Tajrish Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Yaghoob Fatollahi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tarbiat Modares University

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

Tarbiat Modares University

Full name of responsible person

Homa Zamani

Position

Ph.D. student

Latest degree

Master

Other areas of specialty/work

Cell Therapy

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Person responsible for updating data**Contact****Name of organization / entity**

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