Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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
Age
From **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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Tehran
Province
Tehran
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Position
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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
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