Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluate the Safety and Efficacy of Wharton’s Jelly-Derived Mesenchymal Stem Cell Therapy on Sensory-Motor Function and Functional Status in Patients with Chronic and Subacute Traumatic Spinal Cord Injury: A Single-Arm Clinical Trial phase 1

Protocol summary

Study aim
To investigate the safety and efficacy of direct injection of mesenchymal stem cells derived from umbilical cord Wharton's jelly into the spinal cord lesion site on improving sensory-motor function and functional status of patients with traumatic spinal cord injury in the chronic or subacute phase.

Design
Clinical trial without control group, single, unblinded (due to the type of study and nature of the intervention), phase 1 on 10 patients

Settings and conduct
This study will be conducted on at least 10 patients with spinal cord injury who refer to Imam Khomeini Hospital in Sari.Due to the single-group design and the nature of the intervention, there is no possibility of blinding patients or investigators.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 and 60 years Definite diagnosis of traumatic spinal cord injury with a specific lesion level (cervical or thoracic levels) At least 3 months (subacute) or maximum 12 months (chronic) since the injury Neurological functional score in levels A to C Stable hemodynamic and metabolic status Written informed consent Exclusion criteria: History of seizures or progressive neurological diseases History of autoimmune disease or immunodeficiency Active systemic or local infection History of taking immunosuppressive or anticancer drugs Pregnancy or breastfeeding Non-cooperation in long-term follow-up

Intervention groups
Intervention group: Direct injection of approximately 1 to 2 million (per kilogram of body weight) of mesenchymal stem cells derived from umbilical cord Wharton's jelly into the spinal cord lesion site as a single injection for 30 minutes.

Main outcome variables
Injection safety, improvement of neurological function, improvement of daily and motor function, changes in spinal cord imaging, improvement of quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180826040869N4**
Registration date: **2026-05-05, 1405/02/15**
Registration timing: **prospective**

Last update: **2026-05-05, 1405/02/15**
Update count: **0**

Registration date
2026-05-05, 1405/02/15

Registrant information

Name
Misagh Shafizad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3336 1700

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-23, 1405/03/02

Expected recruitment end date

2026-07-25, 1405/05/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the Safety and Efficacy of Wharton’s Jelly-Derived Mesenchymal Stem Cell Therapy on Sensory-Motor Function and Functional Status in Patients with Chronic and Subacute Traumatic Spinal Cord Injury: A Single-Arm Clinical Trial phase 1

Public title

Evaluate the Safety and Efficacy of Wharton’s Jelly-Derived Mesenchymal Stem Cell Therapy on Sensory-Motor Function and Functional Status in Patients with Chronic and Subacute Traumatic Spinal Cord Injury: A Single-Arm Clinical Trial phase 1

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of traumatic spinal cord injury with a specific level of injury (cervical or thoracic levels) At least 3 months (subacute) or a maximum of 12 months (chronic) have passed since the injury. Neurological Functional Score Level A to C Stable hemodynamic and metabolic status Written informed consent

Exclusion criteria:

History of seizures or progressive neurological diseases History of autoimmune disease or immunodeficiency Having an active systemic or local infection History of taking immunosuppressive or anticancer drugs Pregnancy or breastfeeding Lack of cooperation in long-term follow-up

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Organizational Research of Imam (RA) Sari Educational and Therapeutic Hospital

Street address

Imam Khomeini Hospital, Amir Mazandarani Street, Imam Square,

City

Sari

Province

Mazandaran

Postal code

4816633131

Approval date

2025-12-13, 1404/09/22

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1404.101

Health conditions studied

1

Description of health condition studied

Chronic and Subacute Traumatic Spinal Cord Injury

ICD-10 code

T09.3

ICD-10 code description

Injury of spinal cord, level unspecified

Primary outcomes

1

Description

Safety of direct injection of mesenchymal stem cells derived from umbilical cord Wharton's jelly into the spinal cord lesion site

Timepoint

Months 1, 3, 6 and 12

Method of measurement

Through clinical examination, routine tests, Magnetic Resonance Imaging (MRI), and patients' self-report.

Secondary outcomes

1

Description

Improved neurological function (American Spinal Injury Association (ASIA) scale)

Timepoint

At baseline, week 2, months 1, 3, 6, and 12

Method of measurement

History and clinical examination

2

Description
Improving daily and motor function
Timepoint
At baseline, week 2, months 1, 3, 6, and 12
Method of measurement
Barthel Index and Spinal Cord Independence Measure (SCIM) Index

3

Description
Spinal cord changes
Timepoint
At baseline, week 2, months 1, 3, 6, and 12
Method of measurement
MRI

4

Description
Improving the quality of life
Timepoint
At baseline, week 2, months 1, 3, 6, and 12
Method of measurement
World Health Organization Quality of Life Questionnaire (WHOQOL-BREF)

Intervention groups

1

Description
Intervention group: Receiving mesenchymal stem cells derived from Wharton's jelly of the umbilical cord at the site of the spinal cord lesion, approximately 1 to 2 million cells (per kilogram of body weight), once, for 30 minutes, injected. The cells are prepared from reliable sources and under good manufacturing principles and quality control.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Misagh Shafizad
Street address
Imam Khomeini Hospital, Amir Mazandarani Street, Imam Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmadali Enayati
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۴۸۱۵۷۳۳۹۷۱
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ahmadali_enayati@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Misagh Shafizad
Position
Associate 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
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