Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigation of safety and efficacy of intrathecal and intravenous injection of umbilical cord-derived mesenchymal stem cells (UC-MSC) in patients with multiple sclerosis

Protocol summary

Study aim

Investigating the safety of intraspinal and intravenous injection of umbilical cord-derived mesenchymal stem cells (UC-MSC) in patients with multiple sclerosis based on the incidence of side effects and EDSS index

Design

Phase 1 clinical trial without randomization, without blinding (open-label) on 5 patients.

Settings and conduct

The study population consists of patients aged 18 to 55 years who are suffering from multiple sclerosis of SPMS type and have not responded to more than one line of treatment, and the EDSS of these patients should be 3 to 6. In addition to their classical treatment, all these 5 patients received 1 x 106 cells/kg of mesenchymal stem cells intravenously and 0.5 x 106 cells/kg intraspinally. Also, all patients received a booster dose of 0.5 x 106 cells/kg. They receive intrathecal injection 3 months later. The mesenchymal stem cells used are derived from the umbilical cord (UC-MSC). The place of study is the MS Clinic of Imam Khomeini Hospital Complex in Tehran.

Participants/Inclusion and exclusion criteria

McDonald's diagnostic criteria for multiple sclerosis. RRMS or SPMS type of multiple sclerosis. The expanded Disability Status Scale (EDSS) is between 3 and 6.

Intervention groups

In addition to their classical treatment, these 5 patients received 1 x 106 cells/kg of mesenchymal stem cells intravenously and 0.5 x 106 cells/kg intraspinally. All patients received a booster dose of 0.5 x 106 cells/kg intravenously. They receive a spinal cord 3 months later. The mesenchymal stem cells used are derived from the umbilical cord (UC-MSC).

Main outcome variables

Side effects; Disability (EDSS); Upper extremity motor skill performance; Cognitive function; Number of new brain lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161212031362N3**
Registration date: **2023-01-18, 1401/10/28**
Registration timing: **prospective**

Last update: **2023-01-18, 1401/10/28**
Update count: **0**

Registration date

2023-01-18, 1401/10/28

Registrant information

Name

Mohammad Hossein Harirchian

Name of organization / entity

Iranian center of neurological research

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigation of safety and efficacy of intrathecal and intravenous injection of umbilical cord-derived mesenchymal stem cells (UC-MSC) in patients with multiple sclerosis

Public title
Investigation of safety and efficacy of intrathecal and intravenous injection of umbilical cord-derived mesenchymal stem cells

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
McDonald's 2017 diagnostic criteria for multiple sclerosis

Exclusion criteria:
Any history of severe disease that interferes with study results, such as cancer, severe kidney disease, liver disease, digestive disease, heart disease, or any uncontrolled disease Cognitive Disorder, Inability in fill out the consent form voluntarily

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **5**

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
Ethic Committee of Neuroscience Institute , Tehran University of Medical Sciences

Street address
Neuroscience Institute, Imam Khomeini Hospital complex; Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Approval date
2022-11-11, 1401/08/20

Ethics committee reference number
IR.TUMS.NI.REC.1401.057

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
The disability degree

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
EDSS index, functional examination of body systems in 8 aspects: pyramidal, cerebellar, brainstem, sensory, urinary and digestive, visual, cerebral and other aspects of a person's ability to walk

2

Description
Walking performance

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
Questionnaire - Timed 25-Foot Walk, the time a person can walk 25 feet, a maximum time of 3 minutes

3

Description
Upper extremity motor skill performance

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
Questionnaire 9 hole peg test, the time that a person can put the pegs in the hole and then take them out of the hole. Maximum time is 5 minutes

4

Description
Cognitive function

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
Paced Auditory Serial Addition Test (PASAT) questionnaire, a number is said every 3 seconds and the person must add two consecutive numbers together. The number of correct answers is between 0-60

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patient with multiple sclerosis; A) Intrathecal injection of mesenchymal stem cells: 1. Patient admission to the hospital. It is better to hospitalize the patients 24 to 48 hours after the injection of mesenchymal stem cells. 2. Mesenchymal stem cells are delivered in 3 to 4 cc of normal saline solution, and the injection should be performed within 6 hours. 3. Before injection, place the solution containing the cells in the room for 20 minutes to reach room temperature. 4. Do not use alcohol or betadine to sterilize the injection area because it damages the cells hit. 5. Shake the solution gently to homogenize the cells. 6. The 24 g spinal needle is placed in the standard position between the 2nd and 5th lumbar vertebra. 7. After collecting 3-5 ccs of CSF sample for baseline analysis, the solution containing mesenchymal stem cells is injected into the CSF with gentle hand pressure within 1 to 2 minutes, and then 1CC Ringer lactate or normal saline is injected. 8. After the cell injection, the patient is placed in Trendelenberg position 10 degrees and every 15 minutes is rotated on its sides for 2 hours to maximize even distribution of cells in the CSF. 9. Antibiotics can be prescribed to prevent meningitis. B) Intravenous injection of mesenchymal stem cells: 1. Patient admission to the hospital. It is better to hospitalize the patients 24 to 48 hours after the injection of mesenchymal stem cells. 2. Mesenchymal stem cells are delivered in 10 ccs of normal saline and 5% albumin solution and must be injected within 6 hours after delivery. 3. Before injection, place the solution containing the cells in the room for 20 minutes to reach room temperature. 4. Gently shake the solution to homogenize the cells. 5. Remove the cells with a 10 cc syringe and inject them into 100 to 200 cc of normal saline serum. 6. The serum should be infused into the patient's vein within 20 minutes. 7. It is recommended to prescribe agonists of H1 and H2 receptors to prevent allergic reactions before injection and monitor patients for 2 hours. 8. Before and after cell injection, patients should receive 5000 units of heparin (10000 units in total).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Iranian Center of Neurological Research

Full name of responsible person
Mohammad hossein Harirchian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mohammad hossein Harirchian

Position
Professor of Neurology

Latest degree
Specialist

Other areas of specialty/work
Neurology

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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
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
Reporting the results of "Investigation of safety and efficacy of intrathecal and intravenous injection of umbilical cord-derived mesenchymal stem cells (UC-MSC) in patients with multiple sclerosis" investigation as

an article

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

It is not possible to access the data for the use of other people.

From where data/document is obtainable

harirchn@hotmail.com harirchm@tums.ac.ir

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

Within one month after the request, your request will be reviewed and the result will be announced.

Comments