

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 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

Tehran University of Medical Sciences

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

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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