Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Safety assessment of intrathecal and intravenous mesenchymal umbilical cord-derived stem cells in multiple sclerosis patients

Protocol summary

Study aim

Evaluate the safety of simultaneous intrathecal and intravenous administration of umbilical cord-derived mesenchymal stem cells (MSCs) in patients with MS.

Design

This study is designed as a phase I, randomized clinical trial aimed primarily at evaluating the safety of simultaneous intrathecal and intravenous administration of umbilical cord-derived mesenchymal stem cells in patients with MS. The study sample size will consist of 5 patients selected according to the predefined inclusion and non-inclusion criteria. Randomization will be performed using a simple randomization method through the RAND function in Microsoft Excel. All participants will receive the same intervention and will be followed for 12 months regarding clinical, laboratory, and imaging safety outcomes.

Settings and conduct

Patients with MS were referred to the Baqiatallah hospital

Participants/Inclusion and exclusion criteria

Patients with a definite diagnosis of Multiple Sclerosis (MS) according to the 2017 McDonald criteria, aged 18–55 years, with mild to moderate disability (EDSS score 1–6), no acute relapse within the previous 3 months, and written informed consent will be included in the study. Non-inclusion Criteria: Patients with pregnancy or breastfeeding, concomitant autoimmune or chronic diseases, use of immunosuppressive drugs within the previous 3 months, or unwillingness to continue participation will not be included in the study.

Intervention groups

Just one group

Main outcome variables

Adverse events and treatment safety; changes in Expanded Disability Status Scale (EDSS); timed 25-foot walk test; renal function (BUN, creatinine); liver function (AST, ALT, ALKP, bilirubin); hematological indices (WBC, RBC, platelet); inflammatory markers; number of brain plaques detected on MRI; serum neurofilament light chain (NFL) levels; inflammatory cytokines; vital signs; EKG findings; urinalysis results.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251207068238N1**
Registration date: **2026-05-29, 1405/03/08**
Registration timing: **prospective**

Last update: **2026-05-29, 1405/03/08**
Update count: **0**

Registration date

2026-05-29, 1405/03/08

Registrant information

Name

Ramtin Naderian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 919 431 3400

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-05, 1405/03/15

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety assessment of intrathecal and intravenous mesenchymal umbilical cord-derived stem cells in multiple sclerosis patients

Public title

Safety assessment of intrathecal and intravenous mesenchymal umbilical cord-derived stem cells in multiple sclerosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definite diagnosis of Multiple Sclerosis according to the 2017 McDonald criteria. Age between 18 and 55 years old. Mild to moderate disability (Expanded Disability Status Scale [EDSS] score between 1 and 6). No acute relapse within the previous 3 months. Provision of written informed consent for participation in the study.

Exclusion criteria:

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)

Randomized

Randomization description

Given the phase I design of the present clinical trial and its primary focus on safety assessment, a very small sample size will be employed. Consistent with several previous phase I studies that included sample sizes ranging from 5 to 8 participants, the sample size for the current study was determined to be five participants. Eligible subjects will be selected from the study population according to the predefined inclusion and exclusion criteria using a randomized double-blind design.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiatallah University of Medical Sciences

Street address

تهران ، میدان ونک ، خیابان ملاصدرا , خیابان شیخ بهایی جنوبی

City

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Province

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Postal code

۱۴۳۵۹۱۵۳۸۱

Approval date

2026-05-18, 1405/02/28

Ethics committee reference number

IR.BMSU.REC.1405.028

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Incidence and severity of adverse events based on CTCAE criteriaChange in EDSS score from baselineChange in Timed 25-Foot Walk Test performanceChange in the number of brain MRI plaquesChange in serum NFL levelsChange in inflammatory cytokine levels

Timepoint

since the first day to 6 months after that

Method of measurement

The following instruments will be used for data collection in this study:Standardized clinical checklist including:* Vital signs (blood pressure, pulse rate, body temperature, respiratory rate, and SpO_2)* Acute post-injection adverse events (headache, nausea, low back pain, seizure, infection)* EDSS assessment performed by an experienced neurologist specialized in MSStandard paraclinical assessments:* Liver function tests (AST, ALT, ALKP, Bilirubin)* Renal function tests (BUN, Creatinine)* Complete blood count (CBC)* ESR and CRP* Fasting blood glucose* Urinalysis (U/A)* Electrocardiography (EKG)Brain MRI with and without gadolinium contrast enhancement:* Interpreted by an expert neuroradiologistSafety monitoring:* Safety Monitoring Form checklist* Monitoring of immediate adverse events (0–24 hours)* Monitoring of delayed adverse events (1 week, 1 month, and 3 months)Validity of Instruments:Not applicable in this study.Reliability and Validity of

Instruments:Content Validity:All instruments and assessments (CBC, LFT, RFT, MRI, EDSS, and EKG) are internationally standardized and approved (FDA-approved / CE-marked) and are routinely used in validated clinical safety protocols; therefore, no additional validation is required.Construct Validity:Measures such as EDSS, MRI findings, and inflammatory biomarkers are among the most established tools for evaluating disease status and treatment safety in MS patients.Reliability:* Inter-rater reliability: EDSS assessments will be performed by the same experienced neurologist to ensure consistency.* Test–retest reliability: Laboratory assessments (CBC, LFT, RFT) and MRI evaluations have established technical reliability and will be performed by the same technicians and radiologist throughout the study.Sample Size and Sample Size Calculation:Given the phase I design of the study and its primary focus on safety evaluation, a small sample size will be used. Consistent with previous similar studies that included 5–8 participants, the sample size of the present study was determined to be 5 patients, selected according to the predefined inclusion and non-inclusion criteria.Statistical Analysis:Data will be reported descriptively using mean, standard deviation, and percentages. Quantitative variables before and after intervention will be compared using paired t-test or Wilcoxon signed-rank test if the data are not normally distributed.Qualitative variables will be analyzed using McNemar or Chi-square tests. In the presence of multiple follow-up time points, Repeated Measures ANOVA or Linear Mixed Models will be applied.For biomarkers (NFL, IL-1β, IL-6, IL-10), logarithmic transformation or non-parametric tests will be used if the distribution is skewed. Correlations between biomarker changes and MRI/questionnaire findings will be assessed using Spearman correlation analysis.A p-value <0.05 will be considered statistically significant in all analyses.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention Group:Patients with Multiple Sclerosis (MS) will receive simultaneous administration of human umbilical cord-derived mesenchymal stem cells (UC-MSCs). The cells will be isolated, expanded, and quality-controlled under Good Manufacturing Practice (GMP) conditions, including sterility, viability, and contamination testing.The intervention consists of:1. Intravenous (IV) administration of UC-MSCs2. Intrathecal (IT) administration of UC-MSCsAll injections will be performed at Baghiatallah Hospital by an experienced neurologist. Following administration, patients will be monitored for immediate and delayed adverse events through clinical assessments, laboratory evaluations, and brain MRI imaging, and will be followed for 12 months.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiatallah Hospital

Full name of responsible person
Ramtin naderian

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Sponsors / Funding sources

1

Sponsor

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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
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Position
Medical Doctor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data will be anonymized and published only if required for scientific or research purposes.
When the data will become available and for how long
No restrictions
To whom data/document is available
Anonymized data may be shared or published, if required, for relevant authorities, stakeholders, and journal reviewers.
Under which criteria data/document could be used
If needed
From where data/document is obtainable
The Correspondent
What processes are involved for a request to access data/document
By Email request
Comments