

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Safety evaluation of umbilical cord derived mesenchymal stem cells in multiple sclerosis patients

Protocol summary

Study aim

Safety evaluation of umbilical cord derived mesenchymal stem cells in multiple sclerosis patients

Design

This study is a phase 1 clinical trial, the main purpose of which is to investigate the safety and efficacy of placental mesenchymal stem cells in 5 patients with secondary progressive MS without blinding.

Settings and conduct

The injection of mesenchymal stem cells intravenously at the rate of one million per kilogram of body weight is performed without stopping the monoclonal antibody drugs at Baqiyatullah Hospital in Tehran.

Participants/Inclusion and exclusion criteria

1) Age between 18 and 55 2) Diagnosed of MS based on the criteria given by McDonalds 3) EDSS score between 2 and 7 after at least 3 months have passed since the last attack 4) secondary progressive patients who are treated with monoclonal antibodies

Intervention groups

At the rate of one million per kilogram of body weight (6*10) stem cells are injected into patients, and this amount is administered intravenously (IV).

Main outcome variables

Side effects of MSCs on neurophysiological functions, clinical symptoms and immunological processes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230806059052N1**

Registration date: **2023-09-18, 1402/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-18, 1402/06/27**

Update count: **0**

Registration date

2023-09-18, 1402/06/27

Registrant information

Name

Mohamad mahdi Esmaeili

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 81261

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-09-13, 1403/06/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety evaluation of umbilical cord derived mesenchymal stem cells in multiple sclerosis patients

Public title

Safety evaluation of stem cells in multiple sclerosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

MS diagnosed based on McDonalds criteria Secondary progressive patients who are treated with monoclonal

antibodies EDSS score between 2 and 7 after at least 3 months have passed since the last attack

Exclusion criteria:

Active proliferative retinopathy Poor diabetes control (HbA1c greater than 8.5) Renal failure (creatinine more than 2.5) Infection (WBC more than 15000 and/or body temperature more than 38 degrees Celsius) Organ transplant history Active malignancy or its history in the past Cardiovascular disease pregnant women Having a positive PCR test for Covid-19 Mental disorders

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

Research Ethics Committees of Baqiyatallah Hospital

Street address

Sheikh Baha'i

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2023-07-23, 1402/05/01

Ethics committee reference number

IR.BMSU.BAQ.REC.1402.031

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 danger and side effects of mesenchymal stem cell transplantation in terms of causing pain

Timepoint

injection day and 1, 3, 6 and 12 months after stem cell injection

Method of measurement

Patient self-report

2

Description

Degree of disability

Timepoint

before injection and 1, 3 and 12 months after stem cell injection

Method of measurement

with EDSS index

3

Description

Safety and side effects of mesenchymal stem cell transplantation in terms of hypersensitivity

Timepoint

injection day and 1, 3, 6 and 12 months after stem cell injection

Method of measurement

Clinical observation

4

Description

The safety of stem cell injection in terms of causing infection and inflammation

Timepoint

injection day and 1, 3, 6 and 12 months after stem cell injection

Method of measurement

CBC ESR CRP

5

Description

The safety of stem cell injection in terms of damage to the liver

Timepoint

injection day and 1, 3, 6 and 12 months after stem cell injection

Method of measurement

AST ALT

6

Description

The safety of stem cell injection in terms of kidney dysfunction

Timepoint

injection day and 1, 3, 6 and 12 months after stem cell injection

Method of measurement

BUN Creatinine U/A

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The tests before the injection are performed on an outpatient basis and the patient is admitted to the hospital on the day of the injection, and the patient will be hospitalized for 24 hours after the injection. Mesenchymal stem cells will be injected at about 1x10⁶ MSC/Kg, which is as follows: Mesenchymal stem cells will be delivered in 10 cc of normal saline and 5% albumin solution and will be injected over a period of 6 hours. Before injection, it will be in the room for 20 minutes to reach the ambient temperature. We will gently shake the solution until the cells are homogenized, remove the cells with a 10 cc syringe and inject 100 to 200 cc of normal saline serum. The serum is infused into the patient's vein within 20 minutes. Patients receive 5000 units of heparin before and after cell injection.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyat Allah Al-Azam Hospital

Full name of responsible person

Dr. Seyyed Javad Hosseini Nejad Anbaran

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Abbas Ali Imani Fuladi

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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

Seyyed Javad Hosseini Nejad Anbaran

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

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Person responsible for updating data

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohamad Mahdi Esmaeili Araghi

Position

MD

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

Not applicable

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

Clinical study report of the research plan ((Evaluation of the safety of mesenchymal stem cells derived from the umbilical cord in the treatment of patients with multiple sclerosis)) in the form of 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

Javadhoseini1360@gmail.com

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