

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Cell therapy using human placenta-derived mesenchymal stem cells (PLMSCs) in patients with Secondary progressive-MS (SPMS): clinical trial phase I

Protocol summary

Study aim

Evaluation of placenta-derived mesenchymal stem cells injection's safety in SPMS patients.

Design

An open-label phase 1 clinical trial to assess safety and Feasibility of PLMSCs on 5 patients with SPMS

Settings and conduct

Placenta-derived mesenchymal stem cells are about 1×10⁶ MSC / Kg by intravenous injection with Rituximab (500-1000mg i.v) in Sina and Shariati hospital

Participants/Inclusion and exclusion criteria

The inclusion criteria: Patients with SPMS, Age between 18–45 years, Disease duration of more than 2 and less than 15 years, Patients who are taking Rituximab drugs. The Exclusion criteria: Pregnant patients, patients with other systemic problems, Patients with positive results from screening tests (HBV, HCV, HIV, HTLV).

Intervention groups

Placenta-derived mesenchymal stem cells are about 1×10⁶ MSC / Kg by intravenous injection in one patient

Main outcome variables

Safety and side effects of MSCs transplantation on neurophysiological functions, clinical symptoms, and immunological procedures.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210614051576N1**

Registration date: **2021-07-25, 1400/05/03**

Registration timing: **retrospective**

Last update: **2021-07-25, 1400/05/03**

Update count: **0**

Registration date

2021-07-25, 1400/05/03

Registrant information

Name

Ameneh Shokati

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2021-06-10, 1400/03/20

Actual recruitment start date

2021-06-11, 1400/03/21

Actual recruitment end date

2021-06-24, 1400/04/03

Trial completion date

2022-09-22, 1401/06/31

Scientific title

Cell therapy using human placenta-derived mesenchymal stem cells (PLMSCs) in patients with Secondary progressive-MS (SPMS): clinical trial phase I

Public title

The effect of MSCs transplantation in the treatment of SPMS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with SPMS Age between 18–45 years Disease duration of 2 - 16 years Patients who are taking Rituximab drugs

Exclusion criteria:

Pregnant patients Patients with positive results from screening tests (HBV, HCV, HIV, HTLV) Patients with other systemic problems.

Age

From **17 years** old to **45 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **5**

Actual sample size reached: **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

Iran National committee for Ethics in Biomedical research

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran

City

Tehran

Province

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1467664961

Approval date

2021-05-31, 1400/03/10

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.197

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

Safety and side effects of PLMSCs transplantation in terms of pain

Timepoint

baseline, 1,3,6 and 9 months after PLMSCs injection

Method of measurement

self-reported of patients

2

Description

Safety and side effects of high dose PLMSCs transplantation in terms of hypersensitivity.

Timepoint

baseline, 1,3,6 and 9 months after PLMSCs injection

Method of measurement

clinical observation

Secondary outcomes

1

Description

Safety of stem cell transplantation in terms of infection

Timepoint

baseline, 1,3 months after MSCs injection

Method of measurement

CBC, LP

2

Description

Severity of clinical scores

Timepoint

baseline, 1,3,6 and 9 months after MSCs transplantation

Method of measurement

clinical observation by neurologist

3

Description

assessment of neurological function

Timepoint

baseline, 6 and 9 months after After MSCs transplantation

Method of measurement

Magnetic resonance imaging (MRI)

4

Description

assessment of Biomarkers concentrations in peripheral blood of patients

Timepoint

baseline,1,3, 6 months after SCs transplantation

Method of measurement

Flowcytometry

Intervention groups

1

Description

Intervention group: mesenchymal stem cells(MSCs) in a amountof 1×106 MSC/Kg with Rituximab (500-1000mg i.v)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Abdolreza Naser Moghaddasi,Jafar Ai

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Sina Hospital, Hassan Abad Sq., Imam Khomeini St.,
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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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Web page address

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

50

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

Amenesh Shokati

Position

Ph.D. student

Latest degree

Master

Other areas of specialty/work

Applied cell sciences

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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