Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Cell therapy using human endometrial stem cell(hEnSCs) in patients with Secondary progressive-MS(SPMS): Phase I clinical trial

Protocol summary

Study aim
safety of hEnSCs injection in SPMS female patients.
Design
an open label phase 1 clinical trial to assess safety and Feasibility of hEnSCs on 10 female with SPMS
Settings and conduct
Patient recruitment are performed in Sina Hospital.. Endometrial tissue biopsy , hEnSCs isolation, characterization, and culture for IV injection are done and The injection of cells prepared is also done by a neurosurgeon at Sina hospital . Next we evaluate the effect of hEnSCs on patients by assessment of MRI scans on baseline, 6 and 9 months after transplantation.
Participants/Inclusion and exclusion criteria
The inclusion criteria: Women with SPMS Age between 18–45 years , EDSS less than 5.5, Disease duration of more than 2 and less than 15 years, Women who are taking Rituximab drugs The Exclusion criteria: Pregnant patients , patients with other systemic or endometriosis and other uterine problems ,Patients with positive results from screening tests (HBV,HCV,HIV,HTLV)
Intervention groups
The effect of hEnSCs on 10 female with SPMS
Main outcome variables
Efficacy of hEnSCs on neurophysiological functions , Improvement in clinical evaluations and immunological procedures

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190711044175N1**
Registration date: **2019-12-25, 1398/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-23, 1399/12/05**
Update count: **1**
Registration date
2019-12-25, 1398/10/04

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-12-21, 1398/09/30
Expected recruitment end date
2021-12-21, 1400/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Cell therapy using human endometrial stem cell(hEnSCs) in patients with Secondary progressive-MS(SPMS): Phase I clinical trial

Public title
The effect of hEnSCs transplantation in the treatment of SPMS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

(1)Women with SPMS who did not respond to their disease-modifying therapies . (2) Age between 18–45 years (3) EDSS less than 5.5 (4) Disease duration of 2 - 15 years.. (5) Women with at least one delivery (6) Women who are taking Rituximab drugs

Exclusion criteria:

Women under the age of 18 and over 45 years Pregnant patients Patients with positive results from screening tests for hepatitis B and C, human immunodeficiency virus (HIV), and human T-cell lymphotropic virus (HTLV) were also excluded from the study. Patients who had used cytotoxic agents or hormonal therapy within 3 months prior to the study . Patients with endometriosis and other uterine problems

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee for Biological Research of Tehran University of Medical Sciences

Street address

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

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2019-11-29, 1398/09/08

Ethics committee reference number

IR.TUMS.VCR.REC.1398.662

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35-G37

ICD-10 code description

Demyelinating diseases of the central nervous system, multiple sclerosis

Primary outcomes

1

Description

Safety and side effects of hEnSCs transplantation in terms of pain

Timepoint

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

Method of measurement

self-reported of patients

2

Description

Safety and side effects of high dose hEnSCs transplantation in terms of hypersensivity

Timepoint

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

Method of measurement

clinical observation

3

Description

Safety of stem cell transplantation in terms of infection

Timepoint

baseline, 1,3,6 and 9 months after AT-MSCs injection

Method of measurement

CBC, LP

Secondary outcomes

1

Description

Severity of clinical scores

Timepoint

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

Method of measurement

clinical observation by neurologist

2

Description

assessment of neurological function

Timepoint

baseline, 1,3,6 and 9 months after After hEnSCs transplantation

Method of measurement
Magnetic resonance imaging (MRI)

3

Description
assessment of B cell markers CD19+CD20 percentage and MMP9 in peripheral blood of patients
Timepoint
baseline,1,3, 6 and 9 months after SCs transplantation
Method of measurement
Flowcytometery , eliza

Intervention groups

1

Description
Intervention group: endometrial Stem Cells in a amount of 5×106 MSC/Kg with Rituximab (500-1000mg i.v)
Category
Treatment - Drugs

2

Description
Control group: Rituximab (500-1000mg i.v) with placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Somayeh Ebrahimibarough, Abdolreaza Naser Moghaddasi
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Sina Hospital, Hassan Abad Sq., Imam Khomeini St., Tehran - Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Mohammad Ali Sahraian
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Email
rmo@tums.ac.ir
Web page address
http://rmo.tums.ac.ir/index.jsp?fkeyid=&siteid=39&pageid=5658
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
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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