

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Name

Somayeh Ebrahimi-barough

Name of organization / entity

Country

Iran (Islamic Republic of)

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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

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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 hypersensitivity

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

Flowcytometry , eliza

Intervention groups

1

Description

Intervention group: endometrial Stem Cells in a amount of 5×10^6 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

Street address

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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Poursina St. Qods St. Enqelab St

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Web page address

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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

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

Ameneh Shokati

Position

Ph.D. student

Latest degree

Master

Other areas of specialty/work

Applied cell sciences

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Person responsible for updating data

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Position

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Latest degree

Master

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

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