

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Safety and feasibility of systemic intravenous infusion of mesenchymal stem cell-derived exosomes in patients with acute ischemic stroke

Protocol summary

Study aim

This study aims to evaluate the safety and feasibility of intravenous systemic infusion of mesenchymal stem cell-derived exosomes in patients with acute ischemic stroke.

Design

This investigation is a single-arm, open-label, non-randomized, phase I clinical trial, including 9 patients with acute ischemic stroke.

Settings and conduct

Since this study aims to evaluate the safety of exosome therapy, no blinding will be performed. A total of 9 patients will be assigned to the single study intervention arm and will receive intravenous infusion of exosomes as the study intervention.

Participants/Inclusion and exclusion criteria

Patients with age between 18 and 80, diagnosis of acute ischemic stroke based on clinical and radiological evidence, time from onset to injection of 24 to 72 h, and National Institutes of Health Stroke Scale (NIHSS) between 6 and 20 will be included in this study. Patients with lacunar or brainstem stroke, acute intracranial hemorrhage, history of seizure, current or prior traumatic brain injury, history of ischemic stroke or myocardial infarction within the last 6 months, and abnormal renal, hepatic, immunologic, and coagulation profiles will be excluded from the study.

Intervention groups

All patients will be assigned to the single study intervention arm. Patients in the intervention arm will receive the systemic intravenous infusion of mesenchymal stem cell-derived exosomes.

Main outcome variables

The primary outcome measure of the study will be safety profile of the study intervention. Secondary outcome measures will be National Institutes of Health Stroke Scale (NIHSS) and Modified Rankin Scale (mRS).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200502047277N9**

Registration date: **2022-09-17, 1401/06/26**

Registration timing: **prospective**

Last update: **2022-09-17, 1401/06/26**

Update count: **0**

Registration date

2022-09-17, 1401/06/26

Registrant information

Name

saeed oraee yazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 25719

Email address

saeed_o_yazdani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and feasibility of systemic intravenous infusion of mesenchymal stem cell-derived exosomes in patients with acute ischemic stroke	
Public title	Exosome in acute ischemic stroke
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Age between 18 and 80 years Diagnosis of acute ischemic stroke based on clinical and imaging evidence within 24 to 72 h after the onset Baseline National Institutes of Health Stroke Scale (NIHSS) score between 6 and 20
Exclusion criteria:	Diagnosis of lacunar or brainstem stroke Acute intracranial hemorrhage History of seizure or current therapy with anti-epileptic medications Any history of traumatic brain injury Any uncontrolled comorbidity, such as diabetes, hepatic, renal, or cardiac failure Ischemic stroke or myocardial infarction within the last 6 months Abnormal renal, hepatic, immunologic, and coagulation profiles Pregnancy and lactation
Age	From 18 years old to 80 years old
Gender	Both
Phase	1
Groups that have been masked	No information
Sample size	Target sample size: 9
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	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Shahid Beheshti University of Medical Sciences
Street address	Shahid Beheshti University of Medical Sciences ,Shahid Arabi St., Yemen St., Shahid Chamran Highway, Tehran
City	Tehran
Province	Tehran
Postal code	1985717443
Approval date	2022-06-12, 1401/03/22
Ethics committee reference number	IR.SBMU.REC.1401.009
Health conditions studied	
<u>1</u>	
Description of health condition studied	Cerebral infarction
ICD-10 code	I63
ICD-10 code description	Cerebral infarction
Primary outcomes	
<u>1</u>	
Description	Safety profile of the study intervention
Timepoint	Daily during the first 7 days after the injection and weekly until 3-month after the injection
Method of measurement	Monitoring and evaluating the patients regarding the adverse events
Secondary outcomes	
<u>1</u>	
Description	National Institutes of Health Stroke Scale (NIHSS)
Timepoint	1-, 3-, and 6-month after the injection
Method of measurement	Physical examination
<u>2</u>	
Description	Modified Rankin scale (mRS)
Timepoint	1-, 3-, and 6-month after the injection
Method of measurement	Evaluation of patient
Intervention groups	
<u>1</u>	
Description	Intervention group: All patients (n=9) will be assigned to

the single study intervention group. The process of exosome isolation and preparation will be performed in a clinical-grade cleanroom and in compliance with Good Manufacturing Practices (cGMP). Patients will receive 500 µg of exosomes in 100 mL of normal saline as a single intravenous infusion over 30 min. The exosomes will be injected within 24 to 72 h after the onset. Following the injection, all patients will undergo standard care for acute stroke.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Saeed Oraee Yazdani

Street address

Shohadaye Tajrish Hospital, Tajrish Square, Tehran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Afshin Zarghi

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7th Floor, Building Number.2, Shahid Beheshti University of Medical Sciences, Arabi Avenue, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Roosbeh Tavanaei

Position

Research associate

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Functional Neurosurgery Research Center (FNRC), SBMU Shohada-E-Tajrish Educational Hospital, Tajrish Sq., Tehran, Iran

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Person responsible for scientific inquiries

Contact

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Position

Assistant professor

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Person responsible for updating data

Contact

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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