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

1

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

1

Description of health condition studied
Cerebral infarction
ICD-10 code
I63
ICD-10 code description
Cerebral infarction

Primary outcomes

1

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

1

Description
National Institutes of Health Stroke Scale (NIHSS)
Timepoint
1-, 3-, and 6-month after the injection
Method of measurement
Physical examination

2

Description
Modified Rankin scale (mRS)
Timepoint
1-, 3-, and 6-month after the injection
Method of measurement
Evaluation of patient

Intervention groups

1

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 complicance 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
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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
Roozbeh Tavanaei
Position
Research associate
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Person responsible for updating data

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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