

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Safety of allogenic mesenchymal stem cells derived exosome on disability of patients with acute ischaemic stroke: a randomised, open labeled, placebo-controlled, phase 1 trial

Protocol summary

Study aim

Safety assessment of allogenic mesenchymal stem cells derived exosome injection in patients with acute ischemic stroke

Design

Study Phase: Phase 1/Phase 2 Interventional Study
Model: Single Group Assignment Number of Arms: 1
Masking: None (Open Label) Allocation: N/A Enrollment: 5

Settings and conduct

Tajrish Shohada Hospital, Tehran, Iran

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Male or female acute ischemic patients aged 40-80 years with symptoms of acute cerebral infarction of less than 24h from stroke onset. • Patients with a measurable focal neurological that must persist to the time of treatment without clinically meaningful improvement. • Patients must have computerized tomography (CT) and / or magnetic resonance imaging (MRI) compatible with the clinical diagnosis of acute ischemic stroke in the territory of the middle cerebral artery before being included in the study. • Patients must have a score on the NIH Stroke Scale 8-24 • Women of childbearing age should have a negative pregnancy test performed prior to inclusion • Obtaining informed consent signed Exclusion Criteria: • Comatose patients • brain tumour, cerebral oedema with compression of ventricles, cerebellar infarction or brainstem, or intraventricular, intracerebral or subarachnoid hemorrhage. • alcohol use Active infectious disease, including HIV, hepatitis B, Hepatitis • patients with dementia. • Specify clinical conditions • Patients who are participating in another clinical trial. • Inability or unwillingness of individual for giving written informed consent.

Intervention groups

Exosome Injection in patients with acute ischemic stroke

Main outcome variables

Safety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141224020427N4**

Registration date: **2020-11-11, 1399/08/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-11, 1399/08/21**

Update count: **0**

Registration date

2020-11-11, 1399/08/21

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 1250

Email address

leiladehghani@azh.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-09, 1399/08/19

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety of allogenic mesenchymal stem cells derived exosome on disability of patients with acute ischaemic stroke: a randomised, open labled, placebo-controlled, phase 1 trial

Public title

Exosome Therapy in Stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male acute ischemic patients aged 40-80 years with symptoms of acute cerebral infarction of less than 24h from stroke onset. Patients with a measurable focal neurological that must persist to the time of treatment without clinically meaningful improvement Patients must have computerized tomography (CT) and / or magnetic resonance imaging (MRI) compatible with the clinical diagnosis of acute ischemic stroke in the territory of the middle cerebral artery before being included in the study. Patients must have a score on the NIH Stroke Scale 8-24, Obtaining informed consent signed

Exclusion criteria:

Comatose patients. brain tumour, cerebral oedema with compression of ventricles, cerebellar infarction or brainstem, or intraventricular, intracerebral or subarachnoid haemorrhage. alcohol use Active infectious disease, including HIV, hepatitis B, Hepatitis patients with dementia Specify clinical conditions Patients who are participating in another clinical trial. Inability or unwillingness of individual for giving written informed consent.

Age

From **40 years** old to **80 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **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

1

Registry name

ClinicalTrials.gov

Secondary trial Id

NCT03384433

Registration date

2019-07-20, 1398/04/29

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-07-20, 1398/04/29

Ethics committee reference number

IR.SBMU.REC.1398.062

Health conditions studied

1

Description of health condition studied

Ischemic Stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

Fever

Timepoint

3, 30 and 90 days after injection

Method of measurement

Thermometer

2

Description

high sensitivity C-Reactive protein

Timepoint

3, 30, 90 days after injection

Method of measurement

Colorimetric Method

3

Description

Recurrent Stroke

Timepoint

3, 30, 90 days after injection
Method of measurement
computerized tomography (CT)

4

Description
hemorrhagic transformation
Timepoint
3, 30, 90 days after injection
Method of measurement
computerized tomography (CT)

5

Description
Brain Oedema
Timepoint
3, 30 , 90 days after injection
Method of measurement
computerized tomography (CT)

Secondary outcomes

empty

Intervention groups

1

Description
Allogenic Mesenchymal stem cell derived Exosome injection locally in ischemic region under decompress surgery in patient with acute ischemic stroke. The exosome concentration is 200Mg/ml and patients receive one dose for one time
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tajrish hospital
Full name of responsible person
Masoud Soleimani
Street address
Tajrish Squ
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Arash Khojasteh
Street address
Arabi St, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
info@sbmu.ac.ir
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
Saeed Oraee Yazdani
Position
Assisstant Professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Tajrish Hospital, tajrish squ
City
Tehran
Province
Tehran
Postal code
1989934148
Phone

+98 21 25719

Email

saeed_o_yazdani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoud Soleimani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Hematology

Street address

Velenjak, School of Advanced Technologies in Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9847

Email

soleimani.masoud@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Leila Dehghani

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

Street address

Velenjak, School of Advanced Technologies in Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9847

Email

l_dehghani2002@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The non-identifiable individual participant data collected in this study will be shared. Also, The protocol, results, and statistical analysis of the current study will be published in the relevant articles

When the data will become available and for how long

The non-identifiable individual participant data will become available after the publication of the relevant articles

To whom data/document is available

The non-identifiable individual participant data will become available to other researchers in academic institutions

Under which criteria data/document could be used

The non-identifiable individual participant data can only be used for research

From where data/document is obtainable

The non-identifiable individual participant data will be obtainable by sending an e-mail to Prof.Masoud Soleimani (Email: Soleimani.masoud@gamil.com)

What processes are involved for a request to access data/document

Other researchers in academic institutions can send their request by e-mail to Prof.Masoud Soleimani (Email: Soleimani.masoud@gamil.com). The data will be sent to them after consulting and approving the research team

Comments