

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of the safety and feasibility of intra-arterial injection of autologous stem cells derived from adipose tissue in stroke patients.

Protocol summary

Summary

1) Objectives: Evaluation of the safety and feasibility intra-arterial injection of autologous stem cells derived from adipose tissue in stroke patients. 2) Design: In this study we will discuss a phase I clinical trial for the safety and feasibility injection of stem cell in patient's stroke. 3) Setting & Conduct: Processing of isolation of stem cells derived from adipose tissue under GMP condition, Conducting quality control tests, intra-arterial infusion of these cells between 7 to 30 days after onset of stroke (one injection of autologous stem cells derived from adipose tissue via intra-arterial route at the dose of 1 million cells/kg in 2 min via angiocatheter during angiography). 4) Inclusion criteria: age 30-80 ; MRI or CT scan with infarct in middle/anterior cerebral artery without hematoma; ischemic stroke within 7 -30 days before; GCS score > 8, NIHSS score 8 to 20, Signed informed consent if the patient is unable to provide meaningful consent their guardian or legal. Exclusion criteria: The patient is in a coma; Evidence on neuroimaging (CT or MRI) of a brain tumor, cerebral edema with midline shift and unwillingness to provide written informed consent. 5) Intervention: Overall 4 patients will be enrolled and autologous stem cells derived from adipose tissue will be injected intra-arterial for all of them. After intervention, NIHSS and MRS score and also MRI will be evaluated. 6) Main outcome measures are Safety and feasibility of intra-arterial injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111427865N2**

Registration date: **2017-02-09, 1395/11/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-09, 1395/11/21

Registrant information

Name

Masoud Mehrpour

Name of organization / entity

Firoozgar General Hospital, Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the safety and feasibility of intra-arterial injection of autologous stem cells derived from adipose tissue in stroke patients.

Public title

Effect of adipose tissue stem cells in stroke patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Age range 30–80 years 2-Time of stroke onset known and treatment could be started within 7 days of onset. If the exact time of stroke is unknown when the symptoms of stroke have been observed to last referred 3-NIHSS score 8 to 20 4-CT and MRI images can approve stroke 5-Negative pregnancy test in women who are of childbearing age 6-Stroke confined to MCA territory on CT or MRI brain scans 7-All the study steps detailed to the patient and if the patient's consciousness the patient's relatives have to be explained 8-Signed informed consent if the patient is unable to provide meaningful consent their guardian or legal representative must give their consent to participate by signing the informed consent document. Exclusion criteria: 1 2-Evidence on neuroimaging (CT or MRI) of a brain tumor, cerebral edema with midline shift and a clinically significant compression of ventricles, cerebellar or brainstem infarction, and intraventricular, intracerebral, or subarachnoid hemorrhage 3-People who have difficulty accessing them in the future 4-Patients with evidence of life-threatening infection including (AIDS, hepatitis and cancer) 5-Renal dysfunction with creatinine .150 mmol/l 6-Before the stroke alone is not able to perform their daily activities 7-Blood glucose levels is not less than 3 mmol or more than 20 mmol 8-Female patients of childbearing potential (unless it is certain that pregnancy is not possible) or breast feeding 9-Patients who are participating in another clinical trial 10-Current drug or alcohol use or dependence that, in the opinion of the site investigator, would interfere with adherence to the study requirements.

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **4**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single 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 Iran University of Medical Sciences

Street address
Besides Milad Tower-Hemat Highway-Tehran

City
Tehran

Postal code

Approval date
2016-11-12, 1395/08/22

Ethics committee reference number
IR.IUMS.REC.1395028575

Health conditions studied

1

Description of health condition studied
stroke

ICD-10 code
I63.5

ICD-10 code description
occlusion and stenosis of cerebral and precerebral arteries, resulting in cerebral infarction

Primary outcomes

1

Description
Score of NIHSS scale

Timepoint
On 2-24 hours, 7 days, 1-3-6-12 month after cell injection

Method of measurement
NIHSS questionnaire (0-42) score

Secondary outcomes

1

Description
Create Rebleeding

Timepoint
On 2-24 hours, 7 days, 1-3-6-12 month after cell injection

Method of measurement
MRI of brain

2

Description
Tumor Formation

Timepoint
Before and after cell injection

Method of measurement
MRI WHOLE BODY DIFFUSION

3

Description

Rate of Epilepsy
Timepoint
 On 24 hours and 7 days after cell injection
Method of measurement
 EEG

4

Description
 MRS score
Timepoint
 On 2-24 hours, 7 days, 1-3-6-12 month after cell injection
Method of measurement
 MRS questionnaire with score 0-6

5

Description
 Evaluation of structural brain function by MRI
Timepoint
 On 2-24 hours, 7 days, 1-3-6-12 month after cell injection
Method of measurement
 Results of volume of infarction and lateral ventricles before and after cell injection by MRI

Intervention groups

1

Description
 injection of Stem cells derived from adipose tissue in the middle cerebral artery.
Category
 Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
 Firozgar hospital
Full name of responsible person
 Dr masod mehrpour
Street address
 Firozgar hospital-Valiasr square-Tehran
City
 Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
 Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
 seyedamirhosseini
Street address
 Besides Milad Tower-Hemat Highway-Tehran
City

Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Vice chancellor for research, Iran University of Medical Sciences
Proportion provided by this source
 100
Public or private sector
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

Contact
Name of organization / entity
 Iran University of Medical Sciences
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty