Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The survey and comparison between intravenous (IV) and intra-arterial (IA) autologous bone marrow mononuclear cells (BM-Mn Cs) therapy on the recovery of sub-acute ischemic stroke patients

Protocol summary

Summary

1) Objectives: Evaluation and comparison between intravenous (IV) and intra-arterial (IA) autologous bone marrow mononuclear cells (BM-MNCs) therapy on the recovery of sub-acute ischemic stroke patients. 2) Design: In this study we will discuss a phase I clinical trial for the safety and feasibility of intra-arterial and intravenous injection of stem cell in patient's stroke. 3) Setting & Conduct: From each patient, 50 ml of bone marrow aspiration is taken in the operating room and transmitted to the blood transfusion organization for the extraction of mononuclear cells. BM-MNCs contain stem cells and quickly transform to firozgar hospital for injection. 4) Inclusion criteria: age30-80 ; 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 to20, 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 bone marrow mononuclear cells stem cells derived from bone marrow will be injected. After intervention, NIHSS and MRS score and also MRI will be evaluated. 6) Main outcome measures are Safety and feasibility of intra-arterial and intravenous injection.

General information

Acronym

stroke- BM-Mn Cs, cell thrapy

IRCT registration information

IRCT registration number: **IRCT2017092527865N3**
Registration date: **2017-10-05, 1396/07/13**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-10-05, 1396/07/13

Registrant information

Name

Masoud Mehrpour

Name of organization / entity

Firoozgar General Hospital, Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-10-01, 1396/07/09

Expected recruitment end date

2017-12-23, 1396/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The survey and comparison between intravenous (IV) and intra-arterial (IA) autologous bone marrow mononuclear cells (BM-Mn Cs) therapy on the recovery of sub-acute ischemic stroke patients

Public title
Effect of intravenous (IV) and intra-arterial (IA) autologous bone marrow mononuclear cells (BM-MNCs) in stroke patients.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age range 30–80 years old; 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; NIHSS score 8 to20; CT and MRI images can approve stroke; negative pregnancy test in women who are of childbearing age; stroke confined to MCA territory on CT or MRI brain scan; all the study steps detailed to the patient and if the patient's consciousness the patient's relatives have to be explained; 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: evidence on neuroimaging (CT or MRI) of a brain tumor, cerebral edema with mid line shift and a clinically significant compression of ventricles, cerebellar or brainstem infarction, and intraventricular, intracerebral, or subarachnoid hemorrhage; people who have difficulty accessing them in the future; patients with evidence of life-threatening infection including (AIDS, hepatitis and cancer); renal dysfunction with creatinine .150 mmol/l; before the stroke alone is not able to perform their daily activities; blood glucose levels is not less than 3 mmol or more than 20 mmol; female patients of childbearing potential (unless it is certain that pregnancy is not possible) or breast feeding; patients who are participating in another clinical trial; 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
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
Iran University of Medical Sciences, Besides Milad Tower, Hemat Highway
City
Tehran
Postal code
Approval date
2016-08-01, 1395/05/11
Ethics committee reference number
IR.IUMS.REC 1395.95-04-117-30030

Health conditions studied

1

Description of health condition studied
Stroke
ICD-10 code
I63.5
ICD-10 code description
Cerebral infarction due to unspecified occlusion or stenosis of cerebral arteries

Primary outcomes

1

Description
Score of NIHSS scale
Timepoint
On 2-24 hours,7days,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, 7days, 1, 3, 6 and 12 months after cell injection
Method of measurement
MRI of brain

2

Description
MRS score

Timepoint
On 2-24 hours, 7days, 1, 3, 6 and 12 months after cell injection
Method of measurement
MRS questionnair with score 0-6

3

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

4

Description
Evaluation of structural brain by MRI
Timepoint
On 2-24 hours, 7 days, 1, 3, 6 and 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
intravenous (IV) and intra-arterial (IA) autologous bone marrow mononuclear cells (BM-MNCs) in stroke patient.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran University of Medical Sciences
Full name of responsible person
Seyyed Amir Hosseini
Street address
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
Seyed Amir Hosseini
Street address
Iran University of Medical Sciences, Besides Milad Tower, Hemat Highway
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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
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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