

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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: 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 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

Iran (Islamic Republic of)

Phone

+98 21 8214 1201

Email address

azeditehrani.f@tak.iums.ac.ir

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 to 20; 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, 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 and 12 months after cell injection

Method of measurement

MRI of brain

2

Description

MRS score

Timepoint

On 2-24 hours, 7 days, 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

Seyyed Amir Hosseini

Street address

Iran University of Medical Sciences, Besides Milad Tower, Hemat Highway

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

Full name of responsible person

Seyyed Amir Hosseini

Position

PhD Student

Other areas of specialty/work

Street address

Besides Milad Tower-Hemat Highway-Tehran

City

Tehran

Postal code

Phone

+98 21 6693 6299

Fax

Email

amirhosseini1358@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyed Amir Hosseini

Position

PhD Student

Other areas of specialty/work

Street address

Iran University of Medical Sciences, Besides Milad Tower, Hemat Highway

City

Tehran

Postal code

Phone

+98 21 6693 6299

Fax

Email

amirhosseini1358@gmail.com

Web page address

+98 21 6693 6299

Fax

Email

amirhosseini1358@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Amir Hosseini

Position

PhD Student

Other areas of specialty/work

Street address

Iran University of Medical Sciences, Besides Milad

Tower, Hemat Highway

City

Tehran

Postal code

Phone

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