Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the safety and feasibility of delivering human umbilical cord mononuclear cells (cbMNCs) via catheter to the proximal end of the lesion artery in patients with sub-acute stroke in the territory of the middle cerebral artery

Protocol summary

Summary

1) Objectives: Evaluation of the safety and feasibility of delivering human umbilical cord mononuclear cells (cbMNCs) via catheter to the proximal end of the lesion artery in patients with sub-acute stroke in the territory of the middle cerebral artery is the main objective of this study 2)Design: In this study we will discuss a phase I clinical trial for the safety and feasibility of cbMNCs on the possible phenotypic changes in patients with sub-acute ischemic stroke.3)Setting & Conduct: Processing of isolation of cbMNCs 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 cbMNCs via intra-arterial route at the dose of 3 million cells/kg in 2 min via angiocatheter during angiography). 4) Inclusion criteria: age 18-75; MRI or CT scan with infarct in middle/anterior cerebral artery without hematoma; ischemic stroke within 7 -30 days before; GCS score > 8; BI score ≤50, NIHSS score ≥7; inability to raise arms to 90 degrees; stable medical condition for more than 48 hours. Exclusion criteria: lacunar syndrome; intubation; posterior circulation stroke; inaccessibility for follow up; allergy to local anesthetic; unwillingness to provide written informed consent 5)Intervention: Overall 4 patients will be enrolled and allogeneic cbMNCs will be injected intra-arterial for all of them. After intervention, NIHSS, MRS and BI score and also MRI will be evaluated. 6) Main outcome measures are Safety and feasibility of allogeneic cbMNCs intra-arterial injection.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016051327865N1**
Registration date: **2016-11-08, 1395/08/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-11-08, 1395/08/18

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Iran University of Medical Sciences; Iranian council for development of Stem cell sciences & Technologies, Vice presidency for Science and Technology

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the safety and feasibility of delivering human umbilical cord mononuclear cells (cbMNCs) via catheter to the proximal end of the lesion artery in patients with sub-acute stroke in the territory of the middle cerebral artery

Public title
The Safety and feasibility of Intra-Arterial Stem Cell Therapy In Patients with Sub-Acute Stroke

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria: age: 18-75; MRI or CT scan with infarct in middle/anterior cerebral artery without hematoma; ischemic storke with 7 -30 days before; Glasgow Coma Scale score >8; BI score of ≤50, National Institute of Health stroke scale (NIHSS) score of ≥7; inability to raise arms to 90 degrees; stable condition more than 48 hours, normal body temperature; normal blood pressure with mean arterial pressure<125 mmHg (with systolic blood pressur>90 mmHg); normal blood sugar<200 mg/dl; normal urea/electrolyte. Exclusion criteria: lacunar syndrome; intubation; posterior circulation stroke; morbidity likely to limit survival to less than 3 years; pre-stroke disability leading to dependence on others for activity of daily living; inaccessibility for follow up; allergy to local anesthetic; unwillingness to provide written informed consent; symptoms suggestive of acute cardiac; hepatic or renal disease; pregnancy; HIV positivity; participation in any other trial; poor access vessel angiography; Fever.

Age
From **18 years** old to **75 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)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

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, Shahid Hemmat Highway

City
Tehran

Postal code
14665-354

Approval date
2016-08-27, 1395/06/06

Ethics committee reference number
IR.IUMS.REC.1395.27803

Health conditions studied

1

Description of health condition studied
Ischemic 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 0, 30th, 90th and 180th days after cell injection

Method of measurement
NIHSS questionnaire (0-42) score

Secondary outcomes

1

Description
Rate of Epilepsy

Timepoint
On 90th and 180th day after injection

Method of measurement
EEG

2

Description
MRS score

Timepoint
On 0, 90th and 180th days after injection

Method of measurement

MRS questionnair with score 0-6

3

Description
BI score
Timepoint
On 0, 90th and 180th days after cell injection
Method of measurement
BI questionnaire with sore (0-100)

4

Description
Evaluation of structural brain function by MRI
Timepoint
On 0, 30th, 90th and 180th days after injection
Method of measurement
Results of volume of infarction and lateral ventricles before and after cell injection by MRI

Intervention groups

1

Description
Intervention: Injection of stem cells into middle cerebral artery during angiography (one injection of cbMNCs via intra-arterial route at the dose of 3 million cells/kg in 2 min)
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar General Hospital, Iran University of Medical Sciences
Full name of responsible person
Masoud Mehrpour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology, Iran University of Medical Sciences
Full name of responsible person
Dr Seyed Ali Javad Moosavi
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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
Vice Chancellor for Research and Technology, Iran University of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Iranian council for development of Stem cell sciences & Technologies, Vice presidency for Science an
Full name of responsible person
Dr. Ramin Heshmat
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Ladan Alley, Sheikh Bahayi Shomali Avenue, Mollasadra Avenue
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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
Iranian council for development of Stem cell sciences & Technologies, Vice presidency for Science an
Proportion provided by this source
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

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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