

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Dec 2019

### 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

###### 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

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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 stroke with 7 -30 days before; Glasgow Coma Scale score >8; BI score of  $\leq 50$ , National Institute of Health stroke scale (NIHSS) score of  $\geq 7$ ; 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 pressure >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

None

### 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

**Street address**

Karimkhan Avenue, Behafarin Street

**City**

Tehran

**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

**Street address**

5th floor, Central Organization of Iran University of Medical Sciences, Shahid Hemmat Highway

**City**

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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

**Street address**

Ladan Alley, Sheikh Bahayi Shomali Avenue, Mollasadra Avenue

**City**

Tehran

**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****Contact****Name of organization / entity**

Department of Neuroscience, Faculty of Advanced Technologies in Medicine, Iran University of Medical

**Full name of responsible person**

Fereshteh Azedi Tehrani

**Position**

PhD Candidate

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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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*