

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

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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 ≤ 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 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

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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

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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

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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

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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**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*