Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Addition of transcranial direct current stimulation to autologus bone marrow mononuclear cells transplantation on modified rankin scale score of patients with acute ischemic stroke: a randomized clinical trial

Protocol summary

Summary

This study, a randomized single blind clinical trial, will be done to test efficacy and safety of autologous bone marrow-derived mononuclear cell transplantation in combination with transcranial direct current stimulation in treatment of acute ischemic stroke. Inclusion criteria will be ischemic stroke patients who are referred within the first 72 hours after symptoms onset. Patients will be excluded if they have history of previous stroke, history of renal or liver insufficiency, or history of cancer or if they suffer from minor strokes. Study population will be ischemic stroke patients, referred to Shariati hospital, if their conditions are compatible with inclusion and exclusion criteria. Sample size will be 15 patients who will be randomized into three groups. Intervention group one will receive bone marrow-derived mononuclear cell transplantation in combination with active transcranial direct current stimulation. The second intervention group will receive bone marrow-derived mononuclear cell transplantation in combination with sham transcranial direct current stimulation. Control group will receive only sham transcranial direct current stimulation. Primary outcome measure will be functional outcome which will be measured by Modified Rankin Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070817867N2**
Registration date: **2014-09-12, 1393/06/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-09-12, 1393/06/21

Registrant information

Name
Shahram Oveisgharan
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-10-01, 1393/07/09

Expected recruitment end date

2015-09-30, 1394/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Addition of transcranial direct current stimulation to autologus bone marrow mononuclear cells transplantation on modified rankin scale score of patients with acute ischemic stroke: a randomized clinical trial

Public title

Combination of stem cell therapy and non-invasive brain stimulation in acute ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Ischemic stroke patients will be included: if they are referred to recruitment center within their first 72 hours after symptoms onset; if they are between 45 to 85 years old; if their cell transplantation procedure get completed within 72 hours after stroke symptoms onset; if their stroke locations are in hemispheres, not in cerebellum or brain stem. Ischemic stroke patients will be excluded: if they have foreign metallic bodies in their head; if they suffer from previous stroke in their history or imaging; if they have history of cancer; if they have moderate to severe lung disease (Chronic Obstructive Pulmonary Disease or Asthma); if they have history of severe heart failure (class IV in the New York Heart Association Functional Capacity); if they have history of previous stem cell transplantation or history of chemotherapies; if they have uncorrected coagulopathy (which is defined as International Normalized Ratio greater than 1.4 or Partial Thromboplastin Time greater than 40 seconds); if they have pre-stroke dementia; if they or their relatives do not sign consents; if they need others' help in activities of daily livings before their stroke; if they are pregnant; if they have history of renal insufficiency (which is defined as serum creatinine greater than 1.4 mg/dl); if they have history of liver insufficiency (which is defined as serum hepatic enzymes more than three times above upper limits of normal ranges); if they have National Institutes of Health Stroke Scale score less than four; if they get scores greater than one in the first question of National Institute of Health Stroke Scale (level of consciousness); if they are involved in another clinical trial;

Age

From **45 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

keshavarz blvd

City

tehran

Postal code

Approval date

2013-11-25, 1392/09/04

Ethics committee reference number

92-02-159-23253-97522

Health conditions studied

1

Description of health condition studied

Ischemic stroke

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes

1

Description

Functional abilities

Timepoint

Time of discharge, month 1, month 3, month 6. month 12

Method of measurement

Modified Rankin Scale

2

Description

Functional abilities

Timepoint

Time of discharge, month 1, month 3, month 6. month 12

Method of measurement

Barthel Index

Secondary outcomes

1

Description

National Institutes of Health Stroke Scale (NIHSS) score

Timepoint

Time of admission, time of discharge, month 1, month 3, month 6. month 12

Method of measurement

National Institutes of Health Stroke Scale

2

Description

Burning due to transcranial direct current stimulation

application

Timepoint

Time of discharge

Method of measurement

questionnaire

Intervention groups

1

Description

First intervention group: a total of two ml/kg bone marrow will be harvested from posterior iliac bone (blood pressure, heart rate, and oxygen saturation will be monitored during and for one hour after the procedure). The bone marrow will be filtered (170 µm blood filter) to remove spicules. The mononuclear cells (BMC) will get enriched by Ficoll-Paque Plus density gradient, and then will be washed by PBS and administered at 1.25% concentration. Transcranial Direct Current Stimulation (tDCS) will be administered since the day after BMC administration twice daily for 10 days. Anode electrode will be placed according to the main neurological deficit and location of lesion in MRI: for upper extremity paresis it will be placed over C3, C4; for lower extremity paresis it will be placed over Cz; for Broca aphasia it will be placed over F7. Cathod electrodes will be placed over contralateral supraorbital area. Stimulation will be delivered by use of a battery-driven constant current stimulator. Stimulation parameters: stimulation will be increased from zero to two miliampere within thirty seconds and will be continued for thirty minutes. Then, it will decrease to zero within another thirty seconds. Stimulation will be transferred to patients' skin by sixteen square meters sponges.

Category

Treatment - Other

2

Description

Control group: transcranial Direct Current Stimulation (tDCS) will be administered since the day after BMC administration twice daily for 10 days. Anode electrode will be placed according to the main neurological deficit and location of lesion in MRI: for upper extremity paresis it will be placed over C3, C4; for lower extremity paresis it will placed over Cz; for Broca aphasia it will be placed over F7. Cathod electrodes will be placed over contralateral supraorbital area. Stimulation will be delivered by use of a battery-driven constant current stimulator. Stimulation parameters: stimulation will be increased from zero to two miliampere within thirty seconds and will be continued for thirty seconds. Then, it will decrease to zero within another thirty seconds. Stimulation will be transferred to patients' skin by sixteen square meters sponges.

Category

Placebo

3

Description

Second intervention group: a total of two ml/kg bone marrow will be harvested from posterior iliac bone (blood pressure, heart rate, and oxygen saturation will be monitored during and for one hour after procedure). The bone marrow will be filtered (170 µm blood filter) to remove spicules. The mononuclear cells (BMC) will get enriched by Ficoll-Paque Plus density gradient, and then will be washed by PBS and administered at 1.25% concentration. Transcranial Direct Current Stimulation (tDCS) will be administered since the day after BMC administration twice daily for 10 days. Anode electrode will be placed according to the main neurological deficit and location of lesion in MRI: for upper extremity paresis it will be placed over C3, C4; for lower extremity paresis it will be placed over Cz; for Broca aphasia it will be placed over F7. Cathod electrodes will be placed over contralateral supraorbital area. Stimulation will be delivered by use of a battery-driven constant current stimulator. Stimulation parameters: stimulation will be increased from zero to two miliampere within thirty seconds and will be continued for thirty seconds. Then, it will decrease to zero within another thirty seconds. Stimulation will be transferred to patients' skin by sixteen square meters sponges.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Shahram Oveisgharan

Street address

Neurology ward, Shariati Hosital, Amirabad St., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Younesian

Street address

Keshavarz blvd., Tehran

City

Tehran

Grant name

Grant code / Reference number

92-02-159-23253

Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Tehran 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
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Web page address

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