# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 Jun 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
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 8889 6696
**Email address**
oveis@razi.tums.ac.ir


**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**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Shahram Oveisgharan
**Position**
Assistant professor of neurology, board of neurology
**Other areas of specialty/work**
**Street address**
Neurology ward, Shariati hospital, Amirabad st.
**City**
Tehran
**Postal code**
**Phone**
+98 21 8490 2390
**Fax**
**Email**
shogh2@yahoo.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Shahram Oveisgharan
**Position**
Assitant professor of neurology, board of neurology
**Other areas of specialty/work**
**Street address**
Neurology ward, Shariati hospital, Amirabad st., Tehran
**City**
Tehran
**Postal code**
**Phone**
+98 21 8490 2390
**Fax**
**Email**
shogh2@yahoo.com
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Shahram Oveisgharan
**Position**
Assistant professor of neurology, board of neurology
**Other areas of specialty/work**
**Street address**
Neurology ward, Shariati hospital, Amirabad st., Tehran
**City**
Tehran
**Postal code**
**Phone**
+98 21 8490 2390
**Fax**
**Email**
shogh2@yahoo.com
**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*