

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The Comparison between the effects of two different treatment protocols of Repetitive Transcranial Magnetic Stimulation (rTMS) on the improvements of verbal fluency in patients with Postcerebrovascular Accident (CVA) motor aphasia

#### Protocol summary

##### Summary

Objective: To determine and compare the effects of two different treatment protocols of repetitive Transcranial Magnetic Stimulation (rTMS) on the improvement of verbal fluency in patients with postcerebrovascular accident (CVA) motor aphasia. Study design: Random, double-blind (patient and interviewing physician), no placebo-controlled, multicenter, phase II trial. Materials and methods (A) Study population: 48 patients with a clinical diagnosis of stroke-induced motor aphasia presenting to Loghman Hospital and a specialized clinic. Inclusion criteria: Right handedness; the diagnosis of stroke; at least one year passed since the stroke; speaking Persian; and at least a primary education Exclusion criteria: Patients under speech therapy Sample size: 48 patients (B) Intervention(s) under study: Protocol I: The first group consists of 24 patients receiving 10 sessions of high-frequency rTMS (10 hertz) equivalent to 1200 pulse in ten minutes in the Broca's speech area of the left hemisphere and subsequently in the same session, low-frequency stimulation (1 hertz) equivalent to 600 pulses in ten minutes in Broca's symmetric area of the right hemisphere. Protocol II: The second group consists of 24 patients receiving 10 sessions of low-frequency rTMS (1 hertz) equivalent to 600 pulses in ten minutes in Broca's symmetric area in the right hemisphere. (C) The intervention time: October 2014 to March 2015 (D) The primary outcome(s): The number of mentioned objects and duration of mentioning objects by the patients will be recorded and compared before and after the rTMS.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014052417814N1**

Registration date: **2014-10-01, 1393/07/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-10-01, 1393/07/09

##### Registrant information

###### Name

Manouchehr Ilkhani

###### Name of organization / entity

Loghman Hakim Hospital/ Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8894 7269

###### Email address

ebrahimi.p@iums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2013-03-21, 1392/01/01

##### Expected recruitment end date

2014-03-20, 1392/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The Comparison between the effects of two different treatment protocols of Repetitive Transcranial Magnetic Stimulation (rTMS) on the improvements of verbal fluency in patients with Postcerebrovascular Accident (CVA) motor aphasia

## Public title

The Comparison between the effects of Two treatment of Postcerebrovascular Accident (CVA) Motor Aphasia

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Right handedness; the diagnosis of stroke; at least one year passed since the stroke; speaking Persian; and at least a primary education;  
Exclusion criteria: Patients under speech therapy

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 48

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

The blindness of this test is such that the patients' tester after rTMS is not aware of facing which protocol and patient, i.e. the verbal tests and rTMS procedures are performed by two independent people.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committe of Shahid Beheshti University of Medical Sciences

##### Street address

School of Medicine, Koodakyar St., Shahryari Sq., Chamran Highway, Tehran

##### City

Tehran

##### Postal code

##### Approval date

2014-06-01, 1393/03/11

## Ethics committee reference number

152

## Health conditions studied

### 1

#### Description of health condition studied

Aphasia

#### ICD-10 code

R47.0

#### ICD-10 code description

Dysphasia and aphasia

## Primary outcomes

### 1

#### Description

Response time

#### Timepoint

Before the study and after rTMS

#### Method of measurement

Quantity criteria

### 2

#### Description

The Number of Photos Names said by the patients

#### Timepoint

Before the study and after rTMS

#### Method of measurement

Quantity criteria

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Alternative stimulation of two motor speech areas of the brain responsible for motor aphasia (the damaged left hemisphere) and its counterparts in the right hemisphere, with high-frequency (10 Hz) and low frequency (1 Hertz)

#### Category

Treatment - Other

### 2

#### Description

The method of stimulating the right hemisphere Broca symmetric with low frequency (1 Hertz)

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Loghman Hakim Hospital

**Full name of responsible person**

Dr. Manouchehr Ilkhani

**Street address**

Loghman Hakim Hospital, Makhsoos St., Lashgar crossroads

**City**

Tehran

### 2

#### Recruitment center

**Name of recruitment center**

Dr. Manouchehr Ilkhani Neurology Clinic

**Full name of responsible person**

Dr. Manouchehr Ilkhani

**Street address**

8th Floor, No. 637, Opposite of Iraq embassy, Vali-Asr Sq.

**City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor of Research, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Afshin Rezghi

**Street address**

6th Floor, Building No.1, Shahid Beheshti University of Medical Sciences, Parvaneh St., Yaman St., Chamran Highway, Tehran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor of Research, Shahid Beheshti 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**

Iran University of Medical Sciences

**Full name of responsible person**

Parvin Ebrahimi

**Position**

PhD, Health services management

**Other areas of specialty/work****Street address**

No. 6, Rashid Yasemi st., Valiasr St., Health management and economics research center, Iran University of Medical sciences

**City**

Tehran

**Postal code****Phone**

+98 21 8867 1614

**Fax**

+98 21 8867 1615

**Email**

ebrahimi.p@iums.ac.ir; parvin\_eb@yahoo.com

**Web page address**

hme.iums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Parvin Ebrahimi

**Position**

PhD, Health services management

**Other areas of specialty/work****Street address**

No. 6, Rashid Yasemi st., Valiasr St., Health management and economics research center, Iran University of Medical sciences

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## Person responsible for updating data

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**Name of organization / entity**

Iran University of Medical Sciences

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**Position**

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management and economics research center, Iran  
University of Medical sciences

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**Web page address**

hme.iums.ac.ir

**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*