

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study on effect of transcranial light stimulation on the linguistic performance of patients with ischemic stroke induced Broca aphasia

#### Protocol summary

##### Study aim

Determination of transcranial light stimulation on the linguistic performance of patients with ischemic stroke induced Broca aphasia

##### Design

A randomized sham controlled clinical trial with a parallel group design of 20 patients, single-blind. For randomization, random option of SPSS.18 will be used.

##### Settings and conduct

In Imam Reza hospital, infrared laser with wavelength of 810 nanometer will be transmitted in intervention group for 6 minutes, 2 times a week, in a period of 6 weeks from the F3 and F4 regions with radiation of 300 mW/cm<sup>2</sup>. In all cases routine speech therapy will be continued.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria :Patients of both genders, age range 18-60 years, right-handed, aphasia induced by stroke, stroke due to upper branch of middle cerebral artery involvement, unilateral stroke, Broca type aphasia and NIHSS stroke severity of 7-15. Exclusion criteria: More than one stroke, seizure, sustained hypotension or hypertension, septic emboli, known hereditary or acquired hemorrhagic diathesis, skin disorder at the site of light transmission, severe mental deficit or other neurological deficit or disorder, life threatening states such as unstable cardiac arrhythmia, pulmonary emboli, gastrointestinal bleeding and pneumonia, and receiving thrombolytic treatment for the acute ischemic stroke.

##### Intervention groups

Intervention group:10 Broca aphasia stroke patients, receiving infrared laser therapy by a device. Control or sham group: 10 Broca aphasia stroke patients, using the device but .laser is off

##### Main outcome variables

Severity of language problem,

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210118050075N1**

Registration date: **2021-04-22, 1400/02/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-22, 1400/02/02**

Update count: **0**

##### Registration date

2021-04-22, 1400/02/02

##### Registrant information

##### Name

Ali Sang nourpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3320 1225

##### Email address

a.sangnour@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-09, 1400/01/20

##### Expected recruitment end date

2021-07-23, 1400/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study on effect of transcranial light stimulation on the linguistic performance of patients with ischemic stroke induced Broca aphasia

#### Public title

Study on effect of photobiomodulation on stroke induced Broca aphasia

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients of both genders Age range 18-60 years Right handedness Aphasia induced by stroke Stroke due to upper branch of middle cerebral artery involvement Unilateral stroke Broca type aphasia NIHSS stroke severity of 7-15

##### Exclusion criteria:

More than one stroke Seizure Sustained hypotension or hypertension Septic emboli Known hereditary or acquired hemorrhagic diathesis Skin disorder at the site of light transmission Severe mental deficit or other neurological deficit or disorder (eg. dementia, multiple sclerosis) Life threatening such as unstable cardiac arrhythmia, pulmonary emboli, gastrointestinal bleeding and pneumonia Receiving thrombolytic treatment for the acute ischemic stroke

#### Age

From **19 years** old to **85 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **20**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

For All referred and eligible patients in order to enter the study will be allocated 2-digit code from 01 to 20. Then will be used ([en.calc-site.com/randoms/grouping](http://en.calc-site.com/randoms/grouping)) website, which its output is as numbers, first 10 codes for sham group and remaining 10 patients will be in intervention group with a 1:1 ratio.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

In intervention group, laser transmission will be applied on F3 and F4 regions (according to EEG standards) by placing the related equipment, but in control or sham group the same protocol will be used but the laser illumination will be inactive. Because the illumination of infrared laser is invisible, the patient is not able to see the light that can suggest the type of intervention.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Local Ethic Committee of Tabriz University of Medical Sciences

##### Street address

No. 2 Central Office of Tabriz University of Medical Sciences, 3th Floor, Gholghasht Street, Azadi Avenue

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614756

#### Approval date

2020-11-08, 1399/08/18

#### Ethics committee reference number

IR.TBZMED.REC.1399.762

## Health conditions studied

### 1

#### Description of health condition studied

Stroke

#### ICD-10 code

I63.9

#### ICD-10 code description

Cerebral infarction, unspecified

### 2

#### Description of health condition studied

Aphasia

#### ICD-10 code

I69.820

#### ICD-10 code description

Aphasia following other cerebrovascular disease

### 3

#### Description of health condition studied

transcranial photobiomodulation

#### ICD-10 code

#### ICD-10 code description

### 4

#### Description of health condition studied

transcranial infrared laser brain stimulation

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

## 1

### Description

Aphasia severity

### Timepoint

At the start of study and 6 weeks later

### Method of measurement

Bilingual aphasia test (BAT)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Infrared laser with wavelength of 810 nanometer will be transmitted in intervention group for 6 minutes, 2 times a week, in a period of 6 weeks from the F3 and F4 regions according to EEG with radiation of 300 mW/cm<sup>2</sup>. In all studied cases, routine speech therapy will be continued in the sessions.

#### Category

Treatment - Devices

### 2

#### Description

In control or sham group, the same process of intervention group will be done but the laser will be off. In all studied cases, routine speech therapy will be continued in the sessions.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza hospital

##### Full name of responsible person

Mehdi Farhoudi

##### Street address

Neurosciences Research Center, Imam Reza Hospital,  
Gholghasht Street, Azadi Avenue

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##### Province

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##### Postal code

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##### Phone

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##### Email

farhoudi\_m@yahoo.com

##### Web page address

<https://nsrc.tbzmed.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Mehdi Farhoudi

##### Street address

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##### Email

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##### Web page address

<https://nsrc.tbzmed.ac.ir/>

#### Grant name

Grant for medical students thesis

#### Grant code / Reference number

64430 در سامانه پژوهان

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tabriz University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Ali Sangnourpour

##### Position

Medical student

##### Latest degree

A Level or less

##### Other areas of specialty/work

Medical Education

##### Street address

Medical Faculty, Gholghasht Street, Azadi Avenue

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Saeed Sadigetegad

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neuroscience

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Sangnourpour

**Position**

Medical Student

**Latest degree**

A Level or less

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Data without participants names as coded data can be available.

**When the data will become available and for how long**

After finishing of the project, analysis and publication of the thesis

**To whom data/document is available**

University and industry researchers

**Under which criteria data/document could be used**

For research to promote the effect of intervention and or designing of the laser system

**From where data/document is obtainable**

Tabriz Neurosciences Research Center

**What processes are involved for a request to access data/document**

After official request and clarification of the needed data and the aims, the data can be available during 1 month if the the project has already finished.

**Comments**

The material and intellectual property rights of the Neurosciences Research Center and the researchers should be considered.