Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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/cm2. 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)

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+98 41 3320 1225

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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 handness 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) 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/cm2. 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
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Neurosciences Research Center, Imam Reza Hospital, Gholghasht Street, Azadi Avenue
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Sponsors / Funding sources

1

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Grant name
Grant for medical students thesis
Grant code / Reference number
در سامانه پژوهان 64430
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
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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.