

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of localization ability of stroke patients during synchronization of extracranial electrical stimulation and mechanical stimulation of fingers.

Protocol summary

Study aim

Observation of the effect of synchronized stimulation method (in the somatosensory region) on improving the tactile localization ability of post-stroke patients.

Design

The experiment is planned in such a way that the participant is blinded by a table and can not observe location of stimulation.

Settings and conduct

15 participants will receive 4 types of stimulation models as described in the intervention section. Due to the patient's hands under the table, the patient is not able to see the location of mechanical stimulation and can not clearly see the location of stimulation on his fingers. The location of the stimulus is detected only by the patient using the tactile sense system and the localization of tactile stimulation is evaluated using questions and answers from the subject about location of the mechanical stimulation.

Participants/Inclusion and exclusion criteria

Patient entry conditions: 1. Stroke patients who have lost some of their detection power. 2. Age range 24 to 70 years. Conditions for non-entry of the patient: 1. The presence of metal objects such as implants, pacemakers, etc. in the patient's body. 2. weighing more than 100 kg. 3. Stroke patients who have the power of detection localization. 4. uncontrolled blood pressure.

Intervention groups

We have 4 intervention groups: 1- Mechanical (tactile) stimulation without electrical stimulation. 2- Mechanical stimulation and electrical stimulation of tDCS type to the primary somatosensory cortex of the patient's brain. 3- Mechanical stimulation and electrical stimulation of tDCS_sham type to the primary somatosensory cortex of the patient's brain. 4. Mechanical stimulation along with electrical stimulation of tDCS to the primary somatosensory cortex of the patient's brain, which we

call tDSC-sync.

Main outcome variables

Synchronized electrical stimulation of brain regions in tactile functions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210827052301N1**

Registration date: **2021-12-11, 1400/09/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-11, 1400/09/20**

Update count: **0**

Registration date

2021-12-11, 1400/09/20

Registrant information

Name

Maryam Ahmadi

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

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+98 41 5224 7414

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2022-01-29, 1400/11/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of localization ability of stroke patients during synchronization of extracranial electrical stimulation and mechanical stimulation of fingers.

Public title

Evaluation of localization ability of stroke patients during synchronization of extracranial electrical stimulation and mechanical stimulation of fingers.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Stroke patients. Stroke patients who have lost some of their detection power. Age range 24 to 70 years. Lack of Tactile Localization.

Exclusion criteria:

The presence of metal objects such as implants, pacemakers, etc. in the patient's body. weighing more than 100 kg. Stroke patients who have localization. uncontrolled blood pressure.

AgeFrom **24 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **15****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Participants are completely blinded to the type of electrical stimulation and are unaware of the location of tactile stimulation or the type of electrical stimulation. To blind the participant, his hand is placed under a table so that he cannot see the location of tactile stimulation.

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University Of Medical Sciences

Street address

Hemmat highway

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Tehran

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Postal code

1449614535

Approval date

2020-02-25, 1398/12/06

Ethics committee reference number

IR.IUMS.REC.1398.1222

Health conditions studied**1****Description of health condition studied**

stroke

ICD-10 code

G46.3

ICD-10 code description

Brain stem stroke syndrome

Primary outcomes**1****Description**

The main outcome variable in this study is synchronized electrical stimulation of brain regions in tactile localization.

Timepoint

The effect of synchronized electrical stimulation of brain areas in tactile localization is measured during experiment.

Method of measurement

The experiment is planned in such a way that the participant is blinded by a table and can not observe location of stimulation. In this case, the patient is asked to identify the location of stimulation. Based on this, the number of times the patient correctly identified the location of stimulation is counted.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: In this group, both mechanical and

electrical stimulation of the tDCS type will be applied to the primary somatosensory cortex of the patient's brain.

Category

Treatment - Devices

2

Description

Intervention group 2: In this group, both mechanical and electrical stimulation of tDCS_sham type will be applied to the primary somatosensory cortex of the patient's brain.

Category

Treatment - Devices

3

Description

Intervention group 3: In this group, both mechanical stimulation and electrical stimulation of tDCS type will be applied to the primary somatosensory cortex of the patient's brain, this case is similar to the previous case, except that each time mechanical stimulation is applied, electrical stimulation will be applied and electrical stimulation will be interrupted when mechanical stimulation is stopped. In other words, electrical stimulation will be synchronized with mechanical stimulation, which we call tDSC-sync.

Category

Treatment - Devices

4

Description

Intervention group 4: In this group, only mechanical (tactile) stimulation will be applied and no electrical stimulation will be applied.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person

Maryam Ahmadi

Street address

Behafarin street ,Karimkhan street, Valiast Blvr.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Project Manager of Simulation Systems Laboratory.

Proportion provided by this source

100

Public or private sector

Private

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

The University of Tarbiat Modares

Full name of responsible person

Mohammad Rostami

Position

senior researcher

Latest degree

Master

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

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Full name of responsible person

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Associate professor

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Ph.D.

Other areas of specialty/work

Neuroscience

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Bachelor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available