Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 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

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Iran (Islamic Republic of)

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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.
Age
From **24 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target 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
City
Tehran
Province
Tehran
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
Mohammad Rostami
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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

Dr Zahra Bahmani Dehkordi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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researcher

Latest degree

Bachelor

Other areas of specialty/work

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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