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Robotic hand-assisted Transcranial Magnetic Stimulation therapy for rehabilitation from brain damage caused by stroke

Submission date
19/10/2020

Recruitment status
No longer recruiting

Registration date
23/10/2020

Overall study status
Completed

Last Edited
17/11/2023

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims:
Stroke is a disturbance in local blood supply in the brain resulting in the improper functioning of the body part. There are different approaches to treatment in chronic stroke, such as physiotherapy, brain stimulation, medicines, and robotic devices. The use of two rehabilitation strategies at the same time can facilitate a faster recovery process.
Transcranial magnetic stimulation (TMS) is a noninvasive procedure that uses magnetic fields to stimulate nerve cells in the brain.
Our aim is to combine brain stimulation (TMS) and robotic-assisted physiotherapy that might serve as a relatively more effective treatment plan for rehabilitation of wrist joint and fingers joint of post-stroke patients.

Who can participate?
Patients aged 18 - 70 years, with stroke or paralysis.

What does the study involve?
The study involves giving therapy sessions/interventions (details given in the intervention section) to patients with stroke. Clinical evaluation is done before and after completion of therapy sessions. Clinical data acquisition includes functional MRI, clinical scales, cortical excitability measures, and subjective feedback.

What are the possible benefits and risks of participating?
The information we get from the study will help to improve the functioning of hand with stroke and to increase the understanding of the treatment of stroke. Improvements are expected in upper limb movement and function depending upon the size and location of stroke but might not be directly beneficial to the patients enrolled. No direct risk to patients is involved.

Where is the study run from?
1. All India Institute of Technology, New Delhi
2. Indian Institute of Technology, Delhi

When is the study starting and how long is it expected to run for?
January 2015 to March 2020

Who is funding the study?
Science and Engineering Research Board, Department of Science and Technology, India

Who is the main contact?
Dr. Amit Mehndiratta, amitvmehndiratta@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
YSS/2015/000697

Study information

Scientific Title
Comparison of clinical outcomes of robotic hand exoskeleton assisted Transcranial Magnetic Stimulation therapy with dose-matched conventional upper limb rehabilitation: A Randomized Clinical Trial on patients with stroke

Study objectives

Robotic hand exoskeleton assisted Transcranial Magnetic Stimulation therapy will show higher improvement of distal-function and cortical-excitability in patients with stroke as compared to conventional-rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/07/2015, Institute Ethics Committee, All India Institute of Medical Sciences (Room no. 2, First floor, Old OT Block, Ansari Nagar, New Delhi, 110029, India; +91 11 26594579; email: ethicscommitteeaiims@gmail.com), ref: IEC/NP-99/13.03.2015, RP-02/2015

Study design
Interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Evaluation of clinical outcomes in response to the robotic hand-assisted Transcranial Magnetic Stimulation (TMS) therapy in patients with stroke

Interventions
Patients with stroke are randomly divided into 4 groups:
1. Comparator Agent: Physiotherapy - Patient will be asked to do clinical physiotherapy as prescribed by the therapist
2. Intervention: Robotic exoskeleton Assisted Therapy - Patient will be asked to do robotic-assisted rehabilitation therapy
3. Intervention: TMS integrated with robotic exoskeleton device - Patient will be asked to undergo TMS and robotic-assisted therapy, TMS will be given at 0.1 Hz frequency at 100% Resting Motor Threshold
4. Intervention: TMS therapy - patient will be asked to undergo TMS therapy, TMS will be given at 0.1 Hz frequency at 100% Resting Motor Threshold

The interventions take place 5 days a week for 4 weeks (total 20 sessions)

Assessments will be made before and after 20 therapy sessions.

Randomization:
The clinical trial followed a manual simple randomization method. The clinical recruitment of all patients is done in a group of four patients. Once four patients are recruited, they are allocated a pre-defined sequence. Four patients are then instructed to choose one out of 4 colour cards in that specific sequence. The cards they choose signify the groups they are enrolled in for the study.

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
Robotic Hand exoskeleton Device

Primary outcome measure
At baseline and 4 weeks:
1. Spasticity of wrist joint measured using the Modified Ashworth Scale (MAS)
2. Sequence of stages of recovery post-stroke measured using the Brunnstrom stage (BS)
3. Functional independence of patient in Activity of Daily Living (ADL) measured using the Barthel Index
4. Performance-based sensorimotor function index of whole arm measured using Fugl-Meyer Assessment (FMA)
5. Wrist-joint movement without assistance measured through Active Range of Motion on scale: 0 to 70 degrees
6. Disability measurement using the Modified Rankin Scale
7. Patient experience with the therapy sessions using self-designed subjective questionnaire feedback in terms of use, functionality, ease of use, potential of home-based use, user-friendly etc.
8. User-feedback on the usability, complexity and ease of use measured using an industry based System Usability Scale

Secondary outcome measures
At baseline and 4 weeks:
1. Cortical Excitability measurements:
1.1. Peak to peak amplitude (in microvolts) of Motor Evoked Potential (MEP) response of cortex measured using Transcranial Magnetic Stimulation
1.2. Resting Motor Threshold Intensity (in %) to generate the MEP measured using Transcranial Magnetic Stimulation
1.3. Latency period of MEP (in milliseconds), measured using Transcranial Magnetic Stimulation
2. Functional Magnetic Resonance Imaging measures:
2.1. Number of active voxels in different regions of brain while performing the wrist extension task, measuring neuronal activity
2.2. Volume of activation of brain while performing the wrist extension task, measuring neuronal activity
2.3. Structural MRI, measuring any structural changes in brain

Overall study start date
01/01/2015

Completion date
31/03/2020

Eligibility

Key inclusion criteria
1.18 - 70 years of age
2. Single lesioned, Chronic (3 months - 24 months) stroke
3. Cortical/sub-cortical, Ischemic/Hemorrhagic stroke,
4. Modified Ashworth Scale (1,1+, 2), Brunnstrom stage (3-5), Medical Research Council Scale (2-4),
5. Should have motor cortex MEP >= 10uv in lesion hemisphere,
6. Should have wrist extension EMG activity,
7. Is able to give informed consent
8. Can follow the instruction to execute training task with Mini-Mental Scale (MMS 24 - 30)

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
40

Total final enrolment
43

Key exclusion criteria
1. Contra-indications to TMS
2. Progressive neurological or cognitive disorders impinging with assessment scales

Date of first enrolment
01/10/2015

Date of final enrolment
15/02/2020

Locations

Countries of recruitment
India

Study participating centre

All India Institute of Medical Sciences
Ansari Nagar
New Delhi
India
110029

Study participating centre
Indian Institute of Technology
Hauz Khas
New Delhi
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110016

Sponsor information

Organisation
Science and Engineering Research Board

Sponsor details
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Sponsor type
Government

Website
http://www.serb.gov.in/home.php

ROR
https://ror.org/03ffdsr55

Funder(s)

Funder type
Government

Funder Name
Science and Engineering Research Board

Alternative Name(s)
, SERB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
India

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact journal.

Intention to publish date
01/10/2021

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/09/2019	19/10/2020	Yes	No
Other publications		25/05/2023	17/11/2023	Yes	No
Results article		06/05/2021	17/11/2023	Yes	No
Results article		25/07/2022	17/11/2023	Yes	No