Clinical Trial Details (PDF Generation Date :- Sat, 03 Jun 2023 08:55:24 GMT)

CTRI Number	CTRI/2012/02/002412 [Registered on: 09/02/2012] - **Trial Registered Prospectively**
Last Modified On	21/06/2016
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Physiotherapy (Not Including YOGA)
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Comparison of EMG and footswtch triggered stimulation in stroke patients with foot drop.
Scientific Title of Study	A Comparative, Randomized, Double-blind Pilot Study to Evaluate Re-learning of Ankle function after an intensive 2-week Gait Re-training with Electromyogram (EMG)-triggered or Footswitch (SW)-trigger Functional Electrical Stimulation (FES) in Chronic Stroke patients with foot drop

Secondary IDs if Any

Secondary ID	Identifier
EMG001	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	ALAKANANDA BANERJEE
Designation	Head-Physiotherapy and Rehabilitation
Affiliation	Max Superspeciality Hospital
Address	Max Super Speciality Hospital,1, Press Enclave Road,Saket,New Delhi Max Super Speciality Hospital,1, Press Enclave Road,Saket,New Delhi South DELHI 110017 India
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Monetary support-Department of Physiotherapy and Rehabilitation,Max Super Speciality Hospital, New Delhi

Primary Sponsor

Primary Sponsor Details	
Name	Department of Physiotherapy and RehabilitationMSSHwest
Address	Max Super Speciality Hospital ,1 Press Enclave Road,Saket,New Delhi,India
Type of Sponsor	Private hospital/clinic

Details of Secondary Sponsor

Name	Address
Department of Clinical Neurophysiology georg August University	Dept of Clinical Neurophysiology, Georg-August-University, Robert Koch Strasse 40, Goettingen, germany 37075

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Alakananda Banerjee	Max Super Speciality Hospital,	Dept of Physiotherapy and rehabilitation, 1, Press Enclave Road,Saket South DELHI	9811020093 alokabanerjee26@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Max Healthcare Ethics Comittee	Approved	09/11/2011	Yes

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Chronic Stroke Patients

Intervention / Comparator Agent

Type	Name	Details
Intervention	EMG Triggered FES	Frequency and intensity- as per comfortability of subjects Duration- 30 minutes/day for 6 alternate days means 1800 minutes/arm
Comparator Agent	Footswitch Triggered FES	Frequency and intensity- as per comfortability of subjects Duration- 30 minutes/day for 6 aternate days means 1800 minutes/arm

Inclusion Criteria

Inclusion Criteria	
Age From	21.00 Year(s)
Age To	80.00 Year(s)
Gender	Both

Details	•>6 months from a first clinical non-hemorrhagic or hemorrhagic stroke •Medically stable •Unilateral lower extremity hemi paresis •Ankle dorsiflexor strength of ?4/5 on the MRC scale, while seated •Able to ambulate 16 feet (5 meters) continuously with minimal assistance or less, without the use of an AFO. •AFO is clinically indicated (foot drop during ambulation or inefficient gait patterns) •NMES of the paretic ankle dorsiflexors produces ankle dorsiflexion to neutral without pain. •Full voluntary dorsiflexion of the contralateral ankle •Skin intact on hemiparetic lower extremity •Able to don the FES system. •Able to follow 3-stage commands •Able to recall 2 or3 items after 30 minute .Should volunteer and consent to participate in the study

Exclusion Criteria

Exclusion Criteria	
Details	•Brainstem stroke •Epilepsy •Severely impaired cognition and communication •History of peroneal nerve injury •History of Parkinsons, SCI, TBI, or multiple sclerosis, Uncontrolled seizure disorder •Uncompensated hemi-neglect (extinguishing to double simultaneous stimulation) •Edema of the affected lower extremity •Absent sensation of lower leg and foot •Evidence of deep venous thrombosis or thromboembolism •History of cardiac arrhythmias with hemodynamic instability •Cardiac pacemaker or other implanted electronic system •Botulinum toxin injections to any lower extremity muscle in the last 3 months •Pregnancy

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Participant, Investigator and Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
Improvement in normality of linear envelopes of EMG of tibialis anterior muscle of affected limb.	2 WEEKS

Secondary Outcome

Outcome	Timepoints
Usability rating scale	2 weeks

Target Sample Size	**Total Sample Size=**20 **Sample Size from India=**20 **Final Enrollment numbers achieved (Total)=** **Final Enrollment numbers achieved (India)=**
Phase of Trial	N/A
Date of First Enrollment (India)	15/02/2012
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of	Completed

Trial (India)	
Publication Details	None yet
Brief Summary	This study is a randomized, double blind, pilot study to evaluate the re-learning of ankle function after an intensive 2-week gait re-training with electromyogram (EMG)-triggered or footswitch (SW)-triggered neuromuscular electrical stimulation (FES) in chronic stroke patients suffering from foot drop. In this subjects refereed to the department of physiotherapy and rehabilitation will be randomly allocated to either EMG-triggered or Footswitch-triggered FES group. Both the groups will use customized Walking man II drop stimulator with gait training on Treadmill for 6 minutes for 5 times, thrice a week for two weeks with sufficient rest in between the trials. The motion analysis or camera/video will be conducted only during baseline, and post-intervention visits when the subject will walk voluntarily (without NMES) The user feedback based on Usability Rating Scale for their respective intervention (subject blind to the intervention) will be taken from the subject. A multivariate analysis of variance will be done to see any statistically significant differences between two groups (EMG- triggered FES vs. Footswitch-triggered