

FULL DETAILS (Read-only)

CTRI Number	CTRI/2019/09/021270 [Registered on: 17/09/2019] Trial Registered Prospectively	
Last Modified On:	14/09/2019	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Physiotherapy (Not Including YOGA)	
Study Design	Randomized, Parallel Group, Active Controlled Trial	
Public Title of Study	Electrical brain stimulation along with physical therapy effect on improving function in patients with sub-acute stroke	
Scientific Title of Study	Transcranial direct current stimulation combined with trunk targeted proprioceptive neuromuscular facilitation and its effects on impairments, activity limitations and participation restrictions of subjects with sub-acute stroke: A randomized controlled trial	
Secondary IDs if Any	Secondary ID	Registry
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study) Modification(s)	Name	Ajay Kumar Midde
	Address	Department of Physiotherapy, Krishna Institute of medical Sciences, Ministers road, Secunderabad
	Address	Hyderabad TELANGANA 500003 India
	Phone	00919908167776
	Fax	
	Email	ajaymidde85@gmail.com
Details Contact Person Scientific Query Modification(s)	Name	Ajay Kumar Midde
	Address	Krishna Institute of medical Sciences, Ministers road, Secunderabad
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Source of Monetary or Material Support Modification(s)	Department of Medical rehabilitation Sciences, College of Applied Medical Science, C/3/108, Guraiger, King Khalid University, Abha, 61421, Kingdom of Saudi Arabia												
Primary Sponsor	<table border="1"> <tr> <td>Name</td> <td>King Khalid University</td> </tr> <tr> <td>Address</td> <td>C/3/108, Building C, Guraiger, King Khalid University, Abha, Kingdom of Saudi Arabia</td> </tr> <tr> <td>Type of Sponsor</td> <td>Government medical college</td> </tr> </table>	Name	King Khalid University	Address	C/3/108, Building C, Guraiger, King Khalid University, Abha, Kingdom of Saudi Arabia	Type of Sponsor	Government medical college						
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Countries of Recruitment	India Saudi Arabia												
Sites of Study Modification(s)	<table border="1"> <tr> <td colspan="4" style="text-align: center;">No of Sites = 1</td> </tr> <tr> <td>Contact Person</td> <td>Name of Site</td> <td>Site Address</td> <td>Phone/Fax/Email</td> </tr> <tr> <td>Dr Jaya Shanker Tedla</td> <td>Krishna Institute of Medical Sciences</td> <td>Department of Physiotherapy, 2nd floor, New Building, Ministers Road, Secunderabad Hyderabad</td> <td>7674897379 jtedla@kku.edu.sa</td> </tr> </table>	No of Sites = 1				Contact Person	Name of Site	Site Address	Phone/Fax/Email	Dr Jaya Shanker Tedla	Krishna Institute of Medical Sciences	Department of Physiotherapy, 2nd floor, New Building, Ministers Road, Secunderabad Hyderabad	7674897379 jtedla@kku.edu.sa
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Details of Ethics Committee	<table border="1"> <tr> <td colspan="2" style="text-align: center;">No of Ethics Committees= 1</td> </tr> <tr> <td>Name of Committee</td> <td>Approval Status</td> </tr> <tr> <td>Ethics Committee for Scientific Research</td> <td>Approved</td> </tr> </table>	No of Ethics Committees= 1		Name of Committee	Approval Status	Ethics Committee for Scientific Research	Approved						
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Regulatory Clearance Status from DCGI	<table border="1"> <tr> <td>Status</td> </tr> <tr> <td>Not Applicable</td> </tr> </table>	Status	Not Applicable										
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Health Condition / Problems Studied	<table border="1"> <tr> <td>Health Type</td> <td>Condition</td> </tr> <tr> <td>Patients</td> <td>Cerebral infarction, unspecified</td> </tr> </table>	Health Type	Condition	Patients	Cerebral infarction, unspecified								
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		range of motion exercises and gait training activities.
	Intervention	Conventional Physical Therapy, Trunk targeted proprioceptive neuromuscular facilitation (PNF) In this group, the total intervention will be for one and half hour. It includes one hour of Conventional Physical Therapy and 30 minutes trunk targeted PNF. The PNF exercises were based on functional limitation and capability of an individual patient. The therapist will strictly follow the fundamental principles of the PNF method like manual contact, body position and body mechanics, verbal commands, vision, traction/approximation, stretch, timing, and repetitions. Trunk chopping and lifting patterns, bilateral lower limb/upper limb patterns, combined scapular, and pelvic patterns will be used to facilitate trunk. These exercises will be done in different positions like supine, side-lying, prone, sitting and standing based on patient capabilities. Techniques of PNF are incorporated based on patient requirement but Stabilizing reversals / Rhythmic stabilization are mandatory techniques.
	Intervention	Trans Cranial Direct Current Conventional Physical therapy , Stimulation with Trunk targeted and Proprioceptive Neuro muscular facilitation In this group, the total intervention will be for one and a half hour. It includes 40 minutes of Conventional Physical Therapy, 30 minutes trunk targeted PNF and 20 minutes tDCS. Details of tDCS are provided below. tDCS treatment parameters Machine used Neuro-Conn DC stimulator plus or Sotirex tDCS machine Montage basis International EEG 10 – 20 system Software used to test montage Bonsai—Model Solution Analyzer Montage used Bicephalic Montage Anode on affected side C3-C4 Cathode on unaffected side C3-C4 Pad size 5X5 cm The intensity of the current 2 mA Duration of treatment 20 min Number of sessions per week 4 Total number of treatment weeks 6 Total number of session 24
Inclusion Criteria	Age From	18.00 Year(s)
	Age To	75.00 Year(s)
	Gender	Both
	Details	1. Age range 18-75 years 2. First-time supratentorial stroke diagnosed by MRI/CT scan 3. Between 7 days to 6 months post-stroke 4. Able to understand and follow the commands
ExclusionCriteria	Details	1. Any metals in the cranium/ cochlear implants/ cardiac pacemakers 2. Having an unstable epileptic disorder 3. Associated comorbid diseases like cancer/ HIV/Hepatitis or any other neuromuscular disorders which affect the subjects capability to do exercise
Method of Generating Random Sequence	Stratified block randomization	
Method of	Sequentially numbered, sealed, opaque envelopes	

Concealment					
Blinding/Masking	Participant, Investigator and Outcome Assessor Blinded				
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>TimePoints</th> </tr> </thead> <tbody> <tr> <td>1. Trunk impairment scale measures trunk activity and measured as a clinical test 2. Fugl-Meyer Assessment of Motor Recovery after stroke (FMA) measures upper and lower limb activity and measured as a clinical test 3. 10 Meter Walk Test (10mWT) measures gait speed and measured as a clinical test 4. Timed up and go test measures balance and gait activity 5. Wolf Motor Function Test measures upper limb activity and measured as a clinical test 6. Stroke Specific Quality of life</td> <td>Baseline and after 6 weeks</td> </tr> </tbody> </table>	Outcome	TimePoints	1. Trunk impairment scale measures trunk activity and measured as a clinical test 2. Fugl-Meyer Assessment of Motor Recovery after stroke (FMA) measures upper and lower limb activity and measured as a clinical test 3. 10 Meter Walk Test (10mWT) measures gait speed and measured as a clinical test 4. Timed up and go test measures balance and gait activity 5. Wolf Motor Function Test measures upper limb activity and measured as a clinical test 6. Stroke Specific Quality of life	Baseline and after 6 weeks
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Target Sample Size Modification(s)	Total Sample Size="54" Sample Size from India="27"				
Phase of Trial	Phase 1/ Phase 2				
Date of First Enrollment (India)	17/09/2019				
Date of First Enrollment (Global)	17/09/2019				
Estimated Duration of Trial	Years="0" Months="10" Days="0"				
Recruitment Status of Trial (Global) Modification(s)	Not Yet Recruiting				
Recruitment Status of Trial (India)	Not Yet Recruiting				
Publication Details Modification(s)	Nil				
Brief Summary	Background and study aim: Stroke is the foremost cause of death and disability throughout the world. Combining the neuromodulation capability of Transcranial Direct Current Stimulation (tDCS) with a strong clinical treatment tool like Proprioceptive Neuromuscular Facilitation (PNF) could make excellent improvements in the lives of stroke population. tDCS is a non-invasive, painless brain stimulation treatment that uses direct electrical currents to stimulate specific parts of the brain. A constant, low-intensity current is passed through two electrodes placed over the head which modulates brain cell activity. PNF stretching is an advanced form of flexibility training. It involves the contraction and stretching of muscles. Currently, there is dearth of literature pertaining to this combination of				

tDCS with PNF in improving function and quality of life in subjects with subacute stroke.

The aim of this study is to find the effect of tDCS combined with trunk targeted PNF on impairments, activity limitations and participation restrictions of subjects with sub-acute stroke

Who can participate? Stroke patients aged between 18-75 years who meet the inclusion criteria

What does the study involve? The participants undergo some evaluations, tDCS, and physical exercise treatments over a six week period.

What are the possible benefits and risks of participating? There is a possibility that the patient functional capacity will improve and there is no critical risk of participating in the study Some subjects can feel some fatigue after the exercise

Where is the study run from? King Khalid University, Saudi Arabia

When is the study starting and how long is it expected to run for? May 2019 to May 2020

Who is funding the study? Investigator-initiated and funded

Who is the main contact? Dr. Jaya Shanker Tedla jtledla@kku.edu.sa

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