

The effects of patterned electrical stimulation on the temporal pattern of EMG activity in biceps and triceps during a reaching/retrieval task after stroke

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/10/2017	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Miss Imogen Carter

Contact details

St Georges Hospital Medical School
Centre for Rehabilitation and Ageing
St Georges Hospital Medical School
Cranmer Terrace
London
United Kingdom
SW17 0RE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0236143735

Study information

Scientific Title

The effects of patterned electrical stimulation on the temporal pattern of EMG activity in biceps and triceps during a reaching/retrieval task after stroke

Study objectives

The aims of the project are to assess what effects electrically stimulating weakened triceps in stroke subjects has on a task that includes elements of reach and retrieval compared to not stimulating triceps for the same task. In particular I will be assessing whether electrical stimulation changes the ability of the subject to turn a cranked wheel and will record how smoothly they turn the wheel pre and post intervention (electrical stimulation). Further aims are first, to assess whether stimulating triceps has any effect on peak triceps muscle activity after stimulation, second, to see whether electrically stimulating triceps has any effect on the spatial and temporal parameters and modulation of biceps and triceps EMG activity after stimulation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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

Health condition(s) or problem(s) studied

Cardiovascular: Stroke

Interventions

Overview of planned research and summary of methods used: The research will involve a screening/assessment phase followed by the testing phase and will require subjects to attend

the rehabilitation research laboratory at St. George's hospital for one session only. The methods used will be a randomised pre-test - post-test one group design that will involve a small sample of stroke subjects, 12 in each group.

The concerned communities have not been consulted over the design and details of this research as it is a preliminary study looking at proof of principle for electrical stimulation in the upper limb.

At least 24 stroke patients with upper limb difficulties will be recruited. The stroke subjects will be recruited from outpatient neuro-physiotherapy department at St. George's hospital, and the orthotics clinic at the Wolfson Neuro-Rehabilitation Unit. Subjects will also be recruited via advertisement on boards within St. George's and advert in the local paper.

The lead applicant will inform the physiotherapists at the neuro-outpatient services, at St. George's Hospital and the orthotics clinic, Wolfson Neuro-Rehabilitation Unit about the purpose of the study, and the study criteria physiotherapy discharge reports will then be reviewed to identify any recently discharged patients and clinics ready for discharge who meet the study criteria. The lead applicant will then contact each potential subject. If potential subjects are still attending outpatient physiotherapy clinics then the first contact will be face to face during one of their visits to St. George's NHS Trust. If potential subjects are no longer attending outpatient physiotherapy clinics then the lead applicant will make the first contact by sending information about the study, and informed consent form and a sae. Along with a covering letter explaining how they had been identified. The covering letter will state that the lead applicant will be telephoning them within a week of the date of the letter to discuss any questions they might have about the study before they consider giving written informed consent. The covering letter will also state that the lead researcher will be pleased to answer any questions that they might have about the study and welcomes telephone calls at any time.

Once written informed consent is provided then subjects will be recruited to the study and given an appointment to attend the Rehabilitation Research Laboratory at St. George's.

On their arrival at the Rehabilitation Research Laboratory the subjects will be asked to put on a sleeveless T-shirt (this will be supplied if the subjects do not have one of their own). The contextual Assessment will then be undertaken. It is anticipated that this will take approximately 15 minutes. If the subjects meet the criteria at this point they will be invited to continue the research.

The next stage will include taking measurements of their ability to turn the wheel. This will be split into a baseline, intervention and outcome. Their ability to turn the wheel and EMG activity will be assessed during the both phases A and C. the electrical stimulation will be applied during the intervention phase B.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Magnitude of peak EMG activity in paretic triceps muscle
2. The number of the position bin for peak EMG activity in paretic triceps muscle

3. The temporal-spatial pattern of onset/offset of EMG activity in paretic triceps muscle throughout wheel turning
4. The modulation of biceps/triceps

Secondary outcome measures

Not provided at time of registration

Overall study start date

21/06/2004

Completion date

30/09/2005

Eligibility

Key inclusion criteria

At least 24 stroke patients with upper limb difficulties will be recruited. The stroke subjects will be recruited from the neuro-outpatient physiotherapy department at St. George's hospital, and the orthotics clinic at the Wolfson Neuro-Rehabilitation Unit. They will also be identified on the stroke database.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

24

Key exclusion criteria

1. Receiving physiotherapy for the upper limb whilst involved in this study - as this may influence the results
2. More than 150 degrees flexion contracture of the paretic elbow joint - as this would restrict their ability to turn the wheel
3. Any other neuromusculoskeletal pathology severe enough to contribute to the paretic upper limb impairment and/or disability - as this would influence results
4. Unstable medical condition - subjects should be medically stable to participate
5. Any contraindications to electrical stimulation i.e. pacemaker in situ (Chen et al; 1990), heart arrhythmias, pregnancy, superficial metal implants in the upper limb, cancerous tumour, broken or fragile skin in the areas where electrodes need to be placed (Baker et al. 1979a) known tape allergies, uncontrolled epilepsy - this will rule out any potential adverse effects

Date of first enrolment

21/06/2004

Date of final enrolment

30/09/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St Georges Hospital Medical School

London

United Kingdom

SW17 0RE

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

St George's Healthcare NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration