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Effect of repetitive upper limb sensory stimulation immediately after a stroke

Submission date
20/09/2016

Recruitment status
No longer recruiting

Registration date
26/10/2016

Overall study status
Completed

Last Edited
08/11/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Stroke is a serious, life-threatening medical condition that usually happens when a blood clot or haemorrhage cuts off the blood supply to an area of the brain. Symptoms vary according to how much of the brain is affected and where in the brain the stroke occurs, but include paralysis, muscle weakness and speech difficulties. A stroke can also have an impact on the sufferers' emotions and can lead to anxiety, depression and personality changes. The PULSE study aims to measure whether wearing a device called the Tipstim glove and using a pulse generator for approximately 45 minutes a day can improve the feeling and function of the hand and arm in patients who have difficulties using the upper limbs after a stroke. There are scientific theories that by applying Repetitive Sensory Stimulation (RSS) to the upper limb, the growth of new nerve cells in the brain can be encouraged. This is particularly important for stroke patients where brain cells have been destroyed during the stroke.
In this study, patients who have been treated using the TipStim glove in addition to the conventional treatment after a stroke will be compared to patients who have had conventional treatment only to see whether the glove improves upper limb function in stroke patients.

Who can participate?
Adults (aged at least 18) who have recently had a stroke that has affected the functioning of their upper limbs (arm and hand).

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 receive conventional treatment. Participants in group 2 receive conventional treatment and the Tipstim glove treatment. The glove works by producing electrical impulses; these are felt in the fingers as sensory pulsations.
It can be worn at any time, for example, whilst watching television or reading and the participant doesn’t have to do anything other than wear the glove. Participants are asked to wear the glove at least 45 minutes a day for three months. All participants are assessed at the start of the study, 2 weeks into the study and again 3 months later. Assessments take the form of interviews and physical arm tests.

What are the possible benefits and risks of participating?
Participants who are treated with the Tipstim glove may benefit directly from taking part if the study shows that it improves recovery after stroke. Some patients also find it helpful to be part of a research study and be under regular follow-up. The result of the study will help researchers improve the future treatment/care of stroke patients. Apart from the possible inconvenience of the researcher taking up some of the participant's time, there are no particular risks from taking part. In some individuals following a stroke, the limb is more susceptible and at risk of damage;
•The hand may be swollen and participants may experience changes to the skin of the hand whilst wearing the glove- redness, ulcers, damage/soreness to skin. Some participants may notice a painful shoulder on the affected side or Spasticity or contractures of the affected hand. In rare cases, participants may experience an epileptic fit.

Where is the study run from?
Countess of Chester Hospital, Cheshire (UK)

When is the study starting and how long is it expected to run for?
November 2016 to May 2018

Who is funding the study?
BHR Pharmaceutical (UK)

Who is the main contact?
Professor Kausik Chatterjee
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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
Protocol version 6

Study information

Scientific Title
PULSE - effect of rePetitive Upper Limb Sensory stimulation immediately after a strokE: a pilot randomised controlled trial

Acronym
PULSE

Study objectives
The addition of an intervention for post stroke patients –i.e. Repetitive Sensory Stimulation (RSS) via Tipstim glove plus standard treatment for stroke will prove more beneficial in improving sensory-motor function than standard treatment alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Liverpool Central Research Ethics Committee, 22/11/2016, ref: 16/NW/0771

Study design
Single-centre pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions

Patients will be randomised into one of two groups- the intervention or non-intervention group; this randomisation will be computer generated and stratified according to the National Institute of Health Stroke Score (NIHSS); patients will be allocated according to their arm score- group score of 1/2 or 3/4.

Tipstim glove –the intervention.
The glove (various sizes) will be applied onto the affected hand, attached to the generator and switched on. The pulse sequence will be set individually at the highest threshold the patient can comfortably tolerate for the daily 45 minute session. This level will be recorded on each patient research record. The glove is fitted with tiny microprocessor electrodes which transmit pulses to various areas of the fingertips in a repetitive mode. These may be felt by the patient as tingles and known as sensory stimulation= RSS. The patient is free to move around if mobile, read or watch TV etc. during this 45 minutes. After 45 minutes, the researcher/patient/nurse will switch off device and remove glove and observe any adverse events- redness, swelling etc., and note any comments made by patient. The sessions will continue daily, preferably around the same time for two weeks.

Both groups will continue with standard treatment therapies as per protocol for standard care. Standard care encompasses a variety of interventions. Treatment sessions are carried out by an occupational therapist or physiotherapist or joint occupational therapist/ physiotherapist in the treatment room, in upper limb group, in exercise group, in breakfast club, in washing and dressing activities and on home visits. Rehabilitation of the upper limb includes:

1. Task-specific training/ repeated practice including:
1.1. Repetitive upper limb facilitation in function in meaningful activities of Daily Living (ADL)
1.2. De-weighting before “placing” hemi arm in space
1.3. Positioning in alignment with anticipatory postural adjustment (APA) trunk control
1.4. Scapula stabilisation and tone management
1.5. Splinting of the hand and provision of shoulder supports (Omoneurexa)
1.6.. Postural sets to allow upper limb reach and grasp activities
1.7. Napier Grip practice
1.8. Chedoke outcome measure
1.9. Facilitated “GRASP” repetitive exercises
1.10. Bedside activities including thera-putty and GRASP
1.11. Affolter approach using upper limb for co-ordination
1.12. Sensory stimulation includes:
1.13. Retrograde massage
1.14. Sensory bombardment, stimulate distal key points, open hand for reach and grasp with visual contact of palm and thumb
1.15. Contractual Hand Orientation response
1.16. Passive stretches and facilitation of full range of movement
1.17. Weight bearing and balance co-ordination

For the intervention group, face to face interviews and assessments will take place immediately on recruitment, 2 weeks later on completion of RSS intervention and 3 months later.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tipstim glove

Primary outcome measure
1. Change (improvement) in upper limb function at three months using the Action Research Arm Test score
2. Change (improvement) in upper limb function at three months using the Fugl-Meyer assessment of upper extremity (FMA-UE) test
3. Change (improvement) in upper limb function at three months using the Nine Hole Peg test) test
4. Safety incidence for intervention (RSS) group only:
4.1. Any damage to the skin of the hand including necrosis, ulcers occurring within 30 days of enrolment
4.2. Reasons for prematurely stopping the RSS
4.3. Epileptic seizures
4.4. Painful shoulder in the affected side
4.5. Spasticity or contractures of the affected hand
5. Users' feedback (intervention group only): User's feedback will be collected by organising user's feedback meeting after approximately 10 patients have been through the two weeks of treatment. Altogether four meetings will be organised to gather their feedback. Their feedback will be collected by a semi-structured questionnaire covering the following themes:
5.1. How did they feel about using the RSS?
5.2. How easy was it to use?
5.3. Positive aspects of RSS
5.4. Negative aspects of RSS
5.5. Carers perspective on using RSS- perceived levels of spouse/patient improvement
5.6. Measures of outcomes- plus user perceived levels of improvement- psychological, physical, sensory
5.7. Overall impressions of RSS-would they carry on using it if offered and would they recommend it?

All outcomes are measured at baseline and then again at 2 weeks and 3 months.

Secondary outcome measures
1. Change (improvement) in daily living activities, assessed using the Nottingham Extended Activities of Daily Living (NEADL) score (intervention group only)
2. Change (improvement) of quality of life, assessed using the EUROQoL 5D questionnaire (intervention group only)
3. Change (improvement) in mood, assessed using the BASDEC - Brief Assessment Schedule Depression Cards score (intervention group only)

All outcomes are measured at baseline and then again at 2 weeks and 3 months.

Overall study start date
14/11/2016

Completion date
11/05/2018

Eligibility

Key inclusion criteria
1. Age 18 years or over
2. Male and female
3. Unilateral stroke (both ischaemic and haemorrhagic) with sensory motor arm/hand weakness (2 days to 2 weeks) post stroke
4. Baseline National Institute of Health Stroke Scale (NIHSS) arm motor score of 1-4
5. Pre-stroke modified Rankin Scale (mRS) of 0-3
6. Signed informed consent or witnessed verbal consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
After analysing our local National sentinel audit for stroke data from 1st of April 2015 to 31st of March 2016, we found that 57 patients were meeting the study criteria. Therefore, it would be practical include 40 to 60 patients for this pilot trial over one year two months period.

Total final enrolment
40

Key exclusion criteria
1. Patients with transient ischemic attack with symptoms lasting less than 24 hours
2. No arm weakness
3. History of epilepsy
4. Patients with permanent pacemaker
5, Aphasia, or cognitive impairment that prevented completion of the baseline assessment
6. Patients with dermatitis or oedema of the affected hand

Inclusion in another research study, including another randomised controlled trial, does not automatically exclude a patient from participating in this trial. As long as inclusion in the other study would not confound the results of this trial, co-enrolment will be permissible.

Date of first enrolment
01/12/2016

Date of final enrolment
11/01/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Countess of Chester Hospital
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United Kingdom
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Sponsor information

Organisation
Countess of Chester Hospital NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.coch.nhs.uk/

ROR
https://ror.org/0149cpy58

Organisation
BHR Pharmaceuticals (United Kingdom)

Sponsor details
41 Centenary Business Centre
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United Kingdom
CV11 6RY

Sponsor type
Industry

Website
https://www.bhr.co.uk/

ROR
https://ror.org/0151f9x82

Funder(s)

Funder type
Industry

Funder Name
BHR Pharmaceutical

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
11/05/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study 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	01/07/2019	03/07/2019	Yes	No
HRA research summary			28/06/2023	No	No
Dataset		01/07/2019	08/11/2023	No	No