ISRCTN03493501 https://doi.org/10.1186/ISRCTN03493501

Can trophic electrical stimulation enhance the sensorimotor recovery of the hand following surgical repair of median and/or ulnar nerve lesions?

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/09/2007	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 20/08/2020	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs S Glover

Contact details
Physiotherapy
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0265189655

Study information

Scientific Title
Can trophic electrical stimulation enhance the sensorimotor recovery of the hand following surgical repair of median and/or ulnar nerve lesions?

Study objectives
Trophic electrical stimulation (TES) has been shown to improve the blood supply of muscle tissue where the nerve supply has been damaged (dennervated). TES consists of low frequency and low voltage current which is applied to the affected area through the skin (transcutaneuously). The outcome of a local audit of patients with peripheral nerve injury (PNI) suggests that TES may enhance the sensorimotor recovery of the dennervated area. The main research questions/aims are:
1. To establish the recovery patterns of patients experiencing ulnar and or median nerve transection following surgical repair
2. To establish if the recovery pattern can be enhanced via the utilisation of trophic electrical stimulation
3. Can TES enhance a patients' haptic perception, i.e. ability to perceive an object's size weight and texture?
4. Does the increased attention to the affected limb enhance a participants' recovery?

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)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Sensorimotor recovery

Interventions

The plastic surgeons at UHB have agreed to identify and refer patients directly to the key members of the project (Sue Beale, Clinical Specialist Occupational Therapist, Upper Limb Unit (ULU), Caroline Miller, Clinical Specialist Physiotherapist, ULU Sally Glover, Clinical Specialist Physiotherapist - Neurosciences). The staff within the upper limb treatment unit will be made aware of the research aims and objectives and the requirements of each participant. They will be familiar with the inclusion/exclusion criteria. One of the therapists named above will issue the potential participant with an information leaflet and time allowed for questions/queries. Should they wish to participate in the study, then a full explanation will be given outlining the methods of testing, expectations of their attendance at 6-weekly intervals and the benefits that may be acquired from the data collected within the study. They will have further opportunity to ask relevant questions and raise any concerns. Their informed consent will then be sought, should they wish to participate. An appointment will be made for them to attend the upper limb unit in order for baseline measurements to be taken. At week twelve the participants will be allocated to one of the two groups by an independent observer. This Superintendent Physiotherapist Musculoskeletal Outpatients at UHB, will take on this role. In an attempt to ensure the groups are homogeneous as possible, the participants are matched for age, sex and manual/non-manual occupations. The independent observer will have a crib sheet for each group which will hold information on sex/age/occupation. They will allocate participants based on their demographics into Group A or B. All the researchers and participants will be unaware of which group the participants reside in.

Group A will receive trophic electrical stimulation during week twelve post-operatively. Each participant is instructed in the use of the stimulator which is then applied one hour per day. The participants will only feel the sensation of the stimulation until their sensory nerves accommodate to it, which is normally around ten minutes.

Group B will receive a placebo during week twelve post-operatively. They will apply the same stimulator but will only receive 10 minutes of a different frequency. The sensation perceived by the patient will be the same in both groups.

The participants will be required to attend the upper limb unit at UHB every six weeks to monitor their progress. The outcome measures selected record a subjects' sensory, motor and functional performance.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. Tactile sensation, measured by:
1.1. Touch detection threshold test - Monofilaments. This is composed of lucite rods within nylon threads which bend at a certain force when applied against the skin. This will provide a sensory map of the hand.
1.2. Tactile gnosis - Shape and Texture Identification test (STI). This requires participants to identify 3 shapes and 3 textures in three different sizes without visual input. A participants ability to recognise patterns provides an awareness of their spatial acuity. In the absence of a sophisticated test for texture, the above may be replaced with alternatives as experiments are devised by "The Artificial Finger" project being conducted at The Dept of Psychology, University of Birmingham.

1.3. Finger Proprioception - the ability to sense the position of the fingers will be measured by asking participants to judge the relative size of pairs of cubes, held consecutively between fingers and thumb of the impaired hand. By systematically reducing the size difference between the pairs of cubes, the point at which differences between the cubes begin to be reliably discriminated, will be measured as an index of finger proprioception.
2. Motor control, measured by:
2.1. Mid-pronation grasp - Jamar dynamometer is a sealed hydraulic mechanism that registers force in pounds/kg's and is deemed the most reliable of the tools available to measure the pressure of grip
2.2. Pincer grip - Preston pinch gauge - a pneumatic instrument that depends on compression of air by means of a rubber bulb.
2.3. Grip force - participants will be asked to hold an object between their index and thumb whilst varying loads are applied. Force transducers attached to the object will measure the forces applied by the grasping hand, together with the load forces created by the mass of the object. The participants' ability to modify their grip of the object will be measured as various weights are applied to it.

Secondary outcome measures
1. Function, measured by the nine hole peg test. This is a commercially available test (Smith and Nephew Rehabilitation Division). This consists of a plastic console with a shallow round dish to contain the pegs. The participants will be asked to perform the task of removing the nine pegs from nine holes spaced equally along the console and place them into the dish. The participants are timed from the moment they touch the first peg until the last peg hits the dish.
2. Sollerman Hand Function Test: participants are requested to complete tasks 4, 8 and 10, pick up coins from a flat surface and place in a purse, pick up nuts and do up buttons respectively

Overall study start date
30/04/2007

Completion date
30/04/2008

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Each participant must have experienced a surgical repair of a median and/or ulnar nerve lesion
2. They must have a good understanding of the English language or have an interpreter present, as many of the measurements involve detailed instructions

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2 groups of 20

Key exclusion criteria
1. Extensive tissue loss within the forearm and or hand
2. Subjects who are currently prescribed medication for psychiatric illness
3. Communication difficulties where the subject may be unable to provide reliable understanding of:
3.1. Verbal instructions
3.2. Written instructions
3.3. Verbal responses
3.4. Written responses

The methods of testing used within this study require complex verbal instruction, therefore language impairments may confound any results of the investigation.

Date of first enrolment
30/04/2007

Date of final enrolment
30/04/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health
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
University Hospital Birmingham 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