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Can treatment with electrical stimulation help the recovery of arm function in stroke patients?

Submission date 22/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 24/02/2005	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 23/11/2012	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol

Background and study aims.
Stroke is a common disabling disease that affects many people in the UK. A person will often lose the ability to walk and use their hands following a stroke. Loss of independence and the consequent reduction in the quality of life is often associated with the loss in arm function. We proposed to investigate if treatment with electrical stimulation could be used to make the recovery of arm function easier for people who were at risk of remaining chronically disabled after their stroke.

Who can participate?
All adult patients admitted to the City General Hospital and who had not recovered arm function within two weeks to four weeks of their stroke were eligible to participate. We planned to recruit 90 patients over a two-year period for this study.

What does the study involve?
Patients allocated to the treatment arm were given treatment with electrical stimulation. The equipment that was used for electrical stimulation is very similar to a TENS machine which is used to treat pain. The electrodes that delivered treatment were placed on the surface of the forearm. There were no needles involved. A small electrical current was passed via the electrodes to the patients muscles. This could result in a muscle contraction (the same as you would have when you move your arm actively by yourself) and/or a tingling sensation. We have experience of using this equipment and did not expect it to cause pain or any significant side effects. During the treatment session (maximum time of 30 minutes) patients were required to remain seated.

What are the possible benefits and risks of participating?
Treatment with electrical stimulation may have helped the patient by preventing the development of secondary complications such as pain and limb deformities. As we proposed to recruit only patients who were suitable for the treatment the risks were small.

Where is the study run from?
Keele University and University Hospitals of North Staffordshire

When is the study starting and how long is it expected to run for?
The study started in September 2004 and ended in May 2006.

Who is funding the study?
Action Medical Research and The Barnwood House Trust

Who is the main contact?
Professor Anand Pandyan
a.d.pandyan@keele.ac.uk

Study website
http://www.action.org.uk/research_projects/grant_detail.php?id=236

Contact information

Type(s)
Scientific

Contact name
Dr Anand Pandyan

Contact details
Department of Physiotherapy Studies
Mackay Building
Keele University
Keele
United Kingdom
ST5 5BG
+44 (0)1782 584252
a.d.pandyan@keele.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AP0993

Study information

Scientific Title
Can surface neuromuscular electrical stimulation (sNMES) of the wrist and hand, in conjunction with routine therapy, facilitate recovery of arm function in people with poor prognostic indicators of functional recovery?

Study objectives

Primary objective:
Investigate whether treatment with surface neuromuscular electrical stimulation (sNMES) can facilitate recovery of arm function in people with poor prognostic indicators of arm function.

Secondary objectives:
Investigate whether treatment with sNMES will prevent the development of flexion contractures at the wrist and fingers and the development of upper limb pain, improve quality of life and reduce carer burden and costs (service and patient) associated with the long-term management of stroke patients.

As of 09/01/2009 this record was updated with further information provided by the principal investigator. All amendments can be found under the relevant field with the above update date. Please note that at this time a public title was added to this trial, and the previous scientific title has been moved to the correct location. Please also note that the age and gender of participants was added to the inclusion criteria at this time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 09/01/2009: University Hospital North Staffordshire approved on the 30th June 2004 (ref: 04/Q2604/1)

Study design
Single blind randomised active controlled trial (RCT) with independent assessor

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Stroke with no measurable arm function

Interventions
Control:
Routine hand therapy (for six weeks from recruitment).

Treatment:
Routine therapy (as above) and treatment with surface electrical stimulation to the wrist extensors (three 30-minute sessions a day for six weeks).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in the Action Research Arm Test score at recruitment (2 - 4 weeks post-stroke) and at the end of study (one year post-stroke)

Secondary outcome measures
Added 09/01/2009:
1. Pain
2. Isometric wrist strength
3. Contractures (measured as increased resistance to passive movement)
4. Spasticity (assessed by EMG)
5. "Patient" and "Carer" Burden scores
6. Neglect, monitored using the star cancellation test

Measured at baseline (recruitment), 6 weeks, 12 weeks, 24 weeks and 36 weeks.

Overall study start date
01/09/2004

Completion date
31/05/2006

Eligibility

Key inclusion criteria
All adult patients (over the age of 18 years, either sex) with a first stroke who have no recovery of arm function (defined as a score of 0 in the "Grasp" sub-section of the Action Research Arm Test [ARAT]) at 4 weeks and no contraindication to sNMES.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
Added 09/01/2009:
1. Medically unstable
2. A previous medical history of osteoarthritis, rheumatoid arthritis or soft tissue injuries that have resulted in contractures or reduced range of movement in the wrist and fingers
3. Informed consent or relatives' assent cannot be obtained or is refused

Date of first enrolment
01/09/2004

Date of final enrolment
31/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Physiotherapy Studies
Keele
United Kingdom
ST5 5BG

Sponsor information

Organisation
University Hospital Of North Staffordshire NHS Trust (UK)

Sponsor details
Medical Research Unit
Thornburrow Drive
Hartshill
Stoke-on-Trent
England
United Kingdom
ST4 7QB

Sponsor type
Hospital/treatment centre

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

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research (UK)

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2008		Yes	No
Results article	results	01/10/2012		Yes	No