

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

<b>Submission date</b> 22/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/02/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/11/2012	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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  
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**Study website**  
[http://www.action.org.uk/research\\_projects/grant\\_detail.php?id=236](http://www.action.org.uk/research_projects/grant_detail.php?id=236)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## 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?
<a href="#">Results article</a>	results	01/12/2008		Yes	No
<a href="#">Results article</a>	results	01/10/2012		Yes	No