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

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

# 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

# **Contact information**

# Type(s)

Scientific

### Contact name

Dr Anand Pandyan

### Contact details

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# Additional identifiers

Protocol serial number

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

# Study type(s)

Treatment

# 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(s)

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)

# Key secondary outcome(s))

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.

# 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

# Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

### Sex

All

# 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

United Kingdom

England

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

# Sponsor information

# Organisation

University Hospital Of North Staffordshire NHS Trust (UK)

# Funder(s)

# Funder type

Charity

# **Funder Name**

Action Medical Research (UK)

# Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

# **Funding Body Type**

Private sector organisation

# **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

# Location

**United Kingdom** 

# **Results and Publications**

Individual participant data (IPD) sharing plan

IPD sharing plan summary

**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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes