

# Does surface neuromuscular stimulation (NMES) to the upper limb following stroke improve outcome?

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/10/2010	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N0504108438

# Study information

## Scientific Title

### Study objectives

Upper limb impairment affects 80% of stroke patients, half of whom still experience problems three months later. Surface neuromuscular electrical stimulation (sNMES) after stroke may improve upper limb function but current evidence is inconclusive. We have undertaken a randomised controlled trial (RCT) to evaluate a programme of upper limb sNMES following acute stroke.

### 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

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

Cardiovascular: Stroke

### Interventions

Randomised controlled trial to evaluate NMES. Patients hospitalised due to acute stroke randomised within 10 days to receive NMES or placebo for 4 weeks.

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome measure

Outcomes compared at end of treatment period and at 3 months. The primary outcome measure was the Action Research Arm Test (ARAT) 3 months after stroke.

### **Secondary outcome measures**

Upper limb pain, disability and health status.

### **Overall study start date**

01/11/2001

### **Completion date**

01/01/2004

## **Eligibility**

### **Key inclusion criteria**

Between 1st January 2002 and 29th February 2004, subjects admitted with acute stroke to two stroke units were assessed against eligibility criteria: residence within 15 miles of participating hospitals; within 10 days of stroke onset; new upper limb impairment; medically stable; no cognitive/language impairments or previous upper limb problem likely to influence assessments; no other diagnosis likely to interfere with rehabilitation or significant previous co-morbidity; no contraindication to sNMES. Recruitment to begin at North Tyneside Hospital, funding applied for to extend recruitment to Wansbeck. Randomisation by a central independent telephone computerised service based at the University of Newcastle upon Tyne.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

176

### **Key exclusion criteria**

Not provided at time of registration

### **Date of first enrolment**

01/11/2001

### **Date of final enrolment**

01/01/2004

## **Locations**

### **Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**North Tyneside General Hospital**  
North Shields, Tyne + Wear  
United Kingdom  
NE29 8NH

## Sponsor information

**Organisation**  
Department of Health (UK)

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
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SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.doh.gov.uk>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Northumbria Healthcare NHS Trust (UK)

## 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="#">Thesis results</a>	thesis	31/03/2006		No	No
<a href="#">Results article</a>	Results	01/12/2006		Yes	No