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

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 28/10/2010	**Condition category** Circulatory System	

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
United Kingdom
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?
Thesis results	thesis	31/03/2006		No	No
Results article	Results	01/12/2006		Yes	No