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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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
Upper limb pain, disability and health status.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Northumbria Healthcare NHS Trust (UK)

Results and Publications

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	01/12/2006		Yes	No
Thesis results	thesis	31/03/2006		No	No