

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
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 28/10/2010	Condition category Circulatory System	☐ Statistical analysis plan
		☒ Results
		☐ 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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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