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Therapeutic application of neuro-stimulation in acute dysphagic stroke

Submission date 07/01/2003	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/01/2003	**Overall study status** Completed	
Last Edited 03/10/2014	**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
G108/374

Study information

Scientific Title
A randomised controlled trial of pharyngeal electrical stimulation in the treatment of dysphagia after brain injury

Study objectives
Establish efficacy of pharyngeal stimulation in accelerating swallowing recovery after acute dysphagic stroke.

On 22/07/2008 the following changes were made to the trial record:
1. The anticipated start date was changed from 01/09/2003 to 08/11/2005.
2. The anticipated end date was changed from 31/08/2005 to 31/11/2013.
3. The sources of funding field was changed from 'Medical Research Council (UK) and The Health Foundation (UK) (ref: 1727/1793)' to 'Action Medical Research (UK) (until April 2009) and National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB)'.

On 15/10/2009 the following changes were made to the trial record:
1. The scientific title was added.
2. The sources of funding field was changed from 'Action Medical Research (UK) (until April 2009) and National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) ' to 'National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB)'.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Salford and Trafford Research Ethics Committee, 01/10/2002, ref: 00167. An ethics amendment for the current phase of the study was approved on 08/11/2005.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Acute dysphagic stroke

Interventions
Current interventions as of 05/09/2008:
Subjects are randomised to receive either real or sham pharyngeal electrical stimulation at low frequency. The intensity of the electrical stimulation is determined following the calculation of suitable sensory threshold, tailored to the individual participants. Subjects receive the intervention three times in a week, within a few days following index videofluoroscopy.

Previous interventions:
Real versus sham stimulation

The previous sponsor for this trial (from 01/09/2005 to 31/01/2008) was:
Medical Research Council (UK)
20 Park Crescent
London
W1B 1AL
United Kingdom

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 05/09/2008:
Penetration-aspiration score and swallowing response time, assessed by videofluoroscopy at baseline and 2 weeks after the intervention.

Previous primary outcome measures:
1. Mortality
2. Aspiration pneumonia
3. Swallowing function assessed by videofluoroscopy

Secondary outcome measures
Added as of 05/09/2008:
1. Aspiration pneumonia rates
2. Usage of antibiotics for chest infections
3. Hospital stays
4. Readmission rates
5. Mortality

Total duration of follow-up: 6 months

Overall study start date
08/11/2005

Completion date
30/11/2013

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/09/2008:
Any patient with first event of an anterior circulation stroke (both males and females, no age limits). Patients are recruited within 3 weeks of their admission with stroke. Videofluoroscopy is carried out to determine the degree of airway penetration/aspiration.

Previous inclusion criteria:
Hemispheric stroke and dysphagia

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Inability to give informed consent
2. Serious inter-current illness
3. Major neuromuscular modulating drugs
4. Other neurological diseases
5. Previous dysphagia

Date of first enrolment
08/11/2005

Date of final enrolment
30/11/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
GI Sciences
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
University Research Office
2nd Floor Chrisie Building
University of Manchester
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

Website
http://www.manchester.ac.uk

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB)

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?
Abstract results	abstract from Annual Meeting of the American Gastroenterological Association/Digestive Disease Week:	01/04/2005		No	No
Abstract results	abstract from Annual Meeting of the British Society of Gastroenterology:	01/04/2006		No	No