

# Therapeutic application of neuro-stimulation in acute dysphagic stroke

<b>Submission date</b> 07/01/2003	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/01/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/10/2014	<b>Condition category</b> Circulatory System	<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

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**GI Sciences**

Salford

United Kingdom

M6 8HD

**Sponsor information**

**Organisation**

University of Manchester (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

## 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="#">Abstract results</a>	abstract from Annual Meeting of the American Gastroenterological Association/Digestive Disease Week:	01/04/2005		No	No
<a href="#">Abstract results</a>	abstract from Annual Meeting of the British Society of Gastroenterology:	01/04/2006		No	No