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Non-invasive brain stimulation for dysphagia after acute stroke

Submission date 01/04/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 02/04/2015	**Overall study status** Completed	
Last Edited 28/02/2017	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

A stroke occurs when the blood supply to part of the brain is cut off. Around one in two stroke sufferers will have difficulties with swallowing which can complicate their recovery and reduces quality of life. Swallowing problems happen when the part of the brain that controls swallowing is injured by the stroke itself. Swallowing recovers naturally in a proportion of people when the healthy side of the brain adapts and takes over the control of swallowing. There is new evidence that stimulating the healthy side of the brain can speed up this natural recovery process (called plasticity). The aim of this study is to find out if low current brain stimulation to the healthy side of the brain can speed up swallowing recovery and improve quality of life after stroke, and to establish the most effective dose of the treatment.

Who can participate?

Patients having difficulty swallowing (dysphagia) after having suffered a stroke

What does the study involve?

Not provided at time of registration

What are the possible benefits and risks of participating?

The results of this study will provide evidence for using this new approach for dysphagia rehabilitation. The expectation is that this portable user-friendly non-invasive stimulation will be rapidly rolled out into a larger study for use in rehabilitation and lead into changes in practice at a national level in the NHS.

Where is the study run from?

University of Manchester (UK)

When is the study starting and how long is it expected to run for?

April 2015 to September 2017

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18688

Study information

Scientific Title
Randomised controlled dose response trial of transcranial direct current stimulation for dysphagia after acute stroke

Study objectives
The aim of this research project is to find out if low current brain stimulation to the healthy side of the brain in stroke patients with dysphagia can speed up swallowing recovery and improve quality of life after their stroke and to establish the most effective dose of the treatment.

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=18688

Ethics approval required

Old ethics approval format

Ethics approval(s)
12/NW/0262

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Stroke; Subtopic: Acute Care, Rehabilitation; Disease: Device used, Therapy type

Interventions
Dose response of transcranial direct current stimulation

Intervention Type
Device

Primary outcome measure
Changes in safety of swallowing based on formal assessments

Secondary outcome measures
N/A

Overall study start date
01/04/2015

Completion date
01/09/2017

Eligibility

Key inclusion criteria
1. All patients with dysphagia following acute anterior or posterior cerebral circulation stroke that present dysphagia for the first time, within the first weeks from symptoms and up to 6 weeks post stroke. The presence of dysphagia will be based on the results of screening

procedures by the research team. Patients will be always recruited after 48-72 hours post lesion
2. There is no age limit
3. Patients must be medically stable
4. Lesions have to be verified on imaging techniques, either magnetic resonance (MR) scan or computerised tomography (CT), information which will be collected

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 45; UK Sample Size: 45

Key exclusion criteria
1. Advanced dementia
2. Other neurological conditions that may explain swallowing difficulty (dysphagia)
3. Previous history of dysphagia
4. Presence of cardiac pacemaker of implanted cardiac defibrillator
5. Any metal in the head or eyes
6. Use of medication which decreases seizure threshold
7. A diagnosis other than stroke is suspected (e.g. brain tumour)
8. Any severe concomitant chronic medical condition that compromises cardiac or respiratory status,
9. Significant structural abnormalities of the mouth or throat
10. Patients requiring oxygen treatment will be excluded at point of entry to prevent further compromise to already impaired respiratory system
11. Patients may be reconsidered for recruitment if they are successfully weaned off oxygen treatment

Date of first enrolment
01/04/2015

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Manchester
Clinical Sciences Building,Dept. of GI Sciences
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Sponsor information

Organisation
University of Manchester

Sponsor details
Wythenshawe Hospital
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Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

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