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Electrical muscle stimulation programme for swallowing post stroke

Submission date	Recruitment status	[_] Prospectively registered
24/07/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/07/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2019	Circulatory System	

Plain English summary of protocol

Background and study aims
Yearly rates for stroke in England and Wales exceed 130,000. Of these, 37-78% will experience swallowing problems leading to complications including dehydration, malnutrition, choking, pneumonia and death. It also costs the NHS e.g. tube feeding and medication costs for complications resulting from swallowing difficulties. One of the most common swallowing problems is lifting of the voice box. Previous research on the effectiveness of electrical stimulation in treating swallowing problems has produced mixed results and so there has been a call for further research in order to try and clarify this issue. This study aims to help clarify whether this new treatment is more effective than currently available treatments at improving swallowing after stroke.

Who can participate?
People experiencing swallowing difficulties for at least one month following their stroke are eligible to participate in this study.

What does the study involve?
This study will find out how well the AMPCARE programme works (which combines electrical stimulation with exercises), in improving laryngeal (voice box) elevation and swallowing. Usual care will be used as the comparator (control). Patients will be randomly allocated to either the treatment or control group. The treatment group will receive the AMPCARE Effective Swallowing Programme, with treatment sessions for 30 minutes per day, 5 days per week, for 4 weeks. The control group will receive usual care from Speech & Language Therapists (SLT). Usual care normally involves patient education, dietary modifications (e.g. thickened fluids, pureed diet), adapted head postures and exercise programmes for lip, tongue and throat muscles. Patients can choose to receive treatment in an outpatient setting, or their own home. Other assessments will be completed before and after treatment to measure how well the treatment has worked. Patients will also be asked to complete a questionnaire about acceptability of the programme and impact on their quality of life, and will be contacted by phone after 4 weeks to gather data on longer term treatment effects.

What are the possible benefits and risks of participating?
The potential benefits to patients are improved ability to eat and drink safely as a result of improved swallowing. No significant risks have been identified.

Where is the study run from?
The main study site is Sheffield NHS Teaching Hospitals Foundation Trust, UK. The study is in the process of opening recruitment to other local sites.

When is study starting and how long is it expected to run for?
June 2013 to March 2014

Who is funding the study?
Funding has been secured from AMPCARE LLC, South Yorkshire CLAHRC (Collaboration for Leadership in Applied Health Research & Care) and Devices for Dignity, UK.

Who is the main contact?
1. Dr Sue Pownall (Sue.Pownall@sth.nhs.uk)
2. Lise Teasdale (Lise.Teasdale@sth.nhs.uk)

Contact information

Type(s)
Scientific

Contact name
Dr Susan Pownall

Contact details
Royal Hallamshire Hospital
Glossop Road
Sheffield
United Kingdom
S10 2JF
-
sue.pownall@sth.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14952

Study information

Scientific Title

Efficacy of the AMPCARE ESP protocol in improving swallowing in patients with persistent dysphagia post stroke

Acronym
EMSS

Study objectives
This study aims to determine the treatment efficacy of the AMPCARE ESP treatment protocol for patients with persistent swallowing difficulty post stroke. The main hypothesis is that there will be a significant improvement in the swallowing function of the patients in the intervention group, compared to the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service (NRES) Committee Yorkshire & The Humber Sheffield, Ref: 13 /YH/0100

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Topic: Stroke Research Network; Subtopic: Primary Care, Rehabilitation; Disease: Device used

Interventions
AMPCARE ESP, AMPCARE Effective Swallowing Programme (a combination of electrical stimulation plus specific laryngeal elevation exercises)
A cohort of 30 patients with persistent (>1 month) dysphagia post stroke will be recruited and randomly allocated to either the treatment or control group. The treatment group will receive daily AMPCARE ESP electrical stimulation, combined with dysphagia exercises which focus on laryngeal elevation. The control group will receive usual Speech and Language Therapy dysphagia care. The treatment involves application of electrodes to the submental region (just under the chin) in order to achieve greater laryngeal elevation, as reduced laryngeal elevation is a common factor in dysphagia post stroke. The electrical stimulation will be combined with a

specific regime of carefully targeted exercises (involving work against resistance) in order to promote functional stimulation.

Intervention Type
Mixed

Primary outcome measure
1. Swallowing function, measured by:
1.1. MASA - Mann Assessment of Swallowing Ability (validated tool to give a numerical score of patients swallowing ability)
1.2. FOIS - Functional Oral Intake Scale (well used and psychometrically validated tool to measure change in functional eating abilities of Stroke patients over time)
1.3. Rosenbek PAS - Penetration-Aspiration Scale (validated tool for use during videofluoroscopy to evaluate the presence and severity of aspiration i.e. penetration of food and/or fluid into the airway below the level of the vocal folds)
1.4. SWAL-QOL - Patients' assessment of dysphagia related quality of life (validated tool to allow patients to rate 10 dysphagia related quality of life concepts)
2. Patients will also be asked to rate the tolerability of the treatment. Information on the safety of the treatment protocol will be evaluated by recording of any adverse effects during the study

Timepoint(s): 4 weeks following start of treatment

Secondary outcome measures
Not provided at time of registration

Overall study start date
18/06/2013

Completion date
31/03/2014

Eligibility

Key inclusion criteria
1. Swallowing difficulty which is due to stroke (symptoms should include reduced laryngeal elevation, as determined by videofluoroscopy)
2. These difficulties should have persisted for = 1 month (in order to control for spontaneous recovery and response to usual care)
3. Medical stability
4. Absence of any other neurological disease
5. Availability to participate in a treatment session each weekday (either at home or in clinic) for a 4-week period

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
1. Under 18 years of age
2. Have an implanted electronic device e.g. pacemaker
3. Have moderate/severe cognitive or communication difficulties (as they may be unable to give informed consent, or struggle to understand and comply with treatment instructions)
4. Present with progressive disease
5. Are pregnant
6. Have active cancerous lesions or infections in the treatment site

Date of first enrolment
18/06/2013

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Hallamshire Hospital
Sheffield
United Kingdom
S10 2JF

Study participating centre
Walton Hospital
Whitecotes Lane
Chesterfield
United Kingdom
S40 3HW

Study participating centre
Kendray Hospital
Stroke Rehabilitation Unit
Doncaster Road
Barnsley

United Kingdom
S70 3RD

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

Sponsor details
Royal Hallamshire Hospital
Glossop Road
Sheffield
England
United Kingdom
S10 2JF

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
Collaboration for Leadership in Applied Health Research and Care for South Yorkshire, UK

Results and Publications

Publication and dissemination plan
Article in process of submission. Results have also been presented at UK and international conferences (oral and poster presentations).

We would be happy to accept requests for participant level data from other researchers and consider each request individually in order to ascertain whether the requests meet the consent gained from participants during our study.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2018		Yes	No
HRA research summary			28/06/2023	No	No