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Feasibility study: identification of silent aspiration in acute stroke

Submission date 09/08/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 13/10/2023	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 24/08/2023	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dysphagia (swallowing difficulty) is a common side-effect of stroke, affecting between 50-70% of stroke patients. Patients with silent aspiration (food or drink entering the lung in the absence of a cough response) are approximately 13 times more likely to develop pneumonia than those with normal swallowing. Other consequences of post-stroke dysphagia include increased length of hospital stay and increased mortality secondary to pneumonia. This study aims to determine the feasibility of a pilot study comparing the efficacy of cough reflex testing to identify patients who are at risk of silent aspiration compared with usual care (clinical swallow examination - CSE). Results from this study will inform the feasibility of a definitive study to determine whether CRT is more effective than CSE (or subcomponents of CRT) for the identification of patients at risk of silent aspiration with a long-term view to a potential reduction in the incidence of pneumonia, length of hospital stay and mortality with acute stroke patients.

Who can participate?
Patients with a confirmed or suspected new diagnosis of stroke within 3 days of the onset of their stroke symptoms in an acute stroke unit (Royal Victoria Infirmary, Newcastle)

What does the study involve?
30 patients will be recruited for the feasibility study. Participants will all receive the same care. This includes usual care which involves an observation of them eating and drinking (CSE). They will also receive cough reflex testing (CRT), a test to look at the sensory and motor response of the cough which involves inhaling a cough-inducing solution via a nebuliser and rate acceptability of this test. Participants will also receive a flexible endoscopic evaluation of swallowing (FEES) which is one of the gold standard assessments for the identification of silent aspiration.

What are the possible benefits and risks of participating?
There are no known harmful side effects of CRT. There is a chance that participants may cough in response to this test. This is a normal reaction.
If aspiration (food or liquids entering the airway) occurs during CSE or FEES and causes participants to cough or feel uncomfortable, they will be given as much time as they need to recover. Medical/nursing assistance and/or chest physiotherapy will be provided if required.

FEES may cause a small amount of discomfort or a tickly sensation when the scope is inserted. The tip of the scope will be coated with lubricating gel to help minimise any discomfort. Scope insertion may cause participants to sneeze and on very rare occasions may result in nose-bleeding. Participants will be made aware that they can request for the test to be stopped if they find it too uncomfortable.
Participating in this study is not anticipated to cause participants any disadvantages or discomfort and only includes very small differences from the standard swallow assessment received by all stroke patients on admission to hospital.
It is hoped that findings from this study will have a beneficial impact in helping to more accurately identify stroke patients who are at risk of silent aspiration in the future. The benefit to participants will be that FEES shows whether liquids or foods are being aspirated and whether any particular textures are easier or safer for individual participants to swallow.
Results will be discussed with participants after the assessment and will help to inform participants regarding whether they are safe to eat and drink and, if safe, which textures are most appropriate. If participants subsequently eat and drink the textures they have been recommended, there may be a reduced risk of food and liquids being aspirated and therefore a reduced risk of participants developing aspiration pneumonia.

Where is the study run from?
The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2019 to July 2021

Who is funding the study?
Newcastle upon Tyne Hospitals NHS Charity Bridging Stroke Fund (UK)

Who is the main contact?
Mrs Julie Trimble, j.trimble@nhs.net

Contact information

Type(s)
Principal investigator

Contact name
Mrs Julie Trimble

ORCID ID
https://orcid.org/0000-0002-5691-7147

Contact details
Stroke Team
Level 3 Regent Point
Regent Farm Road
Gosforth
United Kingdom
NE3 3HD
+44 (0)191 2826310
j.trimble@nhs.net

Type(s)
Scientific

Contact name
Mrs Julie Trimble

Contact details
Stroke Team
Level 3 Regent Point
Regent Farm Road
Gosforth
United Kingdom
NE3 3HD
+44 (0)191 2826310
j.trimble@nhs.net

Type(s)
Public

Contact name
Mrs Julie Trimble

Contact details
Stroke Team
Level 3 Regent Point
Regent Farm Road
Gosforth
United Kingdom
NE3 3HD
+44 (0)191 2826310
j.trimble@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
280542

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
09534, IRAS 280542

Study information

Scientific Title

Feasibility study for identification of patients at potential risk of silent aspiration in an acute stroke setting: a comparison of clinical swallow examination and cough reflex testing

Study objectives
This study tests the feasibility and acceptability of introducing cough reflex testing (CRT) and developing a standardized clinical swallowing examination (CSE).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/09/2020, North East - Newcastle & North Tyneside 2 Research Ethics Committee (Meeting held by video-conference via Zoom, Newcastle upon Tyne, -, United Kingdom; +44 (0) 2071048086; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 20/NE/0189

Study design
Single-arm preliminary prospective feasibility study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Stroke

Interventions
This is a single-arm, preliminary, prospective, feasibility study of patients less than 72 h post-stroke, over a 31-day period in a hyperacute stroke unit: the Royal Victoria Infirmary, Newcastle-upon-Tyne, UK, between November 2020 and July 2021. The study tested the feasibility and acceptability of introducing CRT and developing a standardized CSE.

Eligible participants within 72 hours post-stroke were screened by the primary investigator (JT). Patients who were medically unstable, palliative, not alert enough, too agitated, had confirmed or suspected COVID-19, NPO for surgery or had a structural anomaly that could interfere with swallowing were excluded. Prior to further assessment, written consent was obtained from participants or assent was sought from an appropriate consultee for patients who lacked the capacity to consent.

Demographic characteristics were obtained from medical notes, the patient and/or their carers (s).

The index tests (clinical swallowing examination (CSE) and cough reflex testing (CRT)) were completed in random order to account for potential fatigue, before the gold-standard flexible endoscopic evaluation of swallowing (FEES). While blinding would have been preferred, staffing pressures due to the COVID-19 pandemic meant that all assessments were carried out individually with recruited patients face-to-face by the same dysphagia-trained SLT (JT) who (at

the time of the study) had over 13 years of clinical dysphagia experience including 8 years experience in the use of FEES and had received training in dysphagia assessment and management including CSE, FEES and CRT.

Index test assessment: Clinical Swallow Examination (CSE)
CSE was adapted for the purpose of screening for SA from the routine CSE used at the hospital based on a review of the literature relating to clinical identification of silent aspiration. CSE included a trial of oral diet and fluids progressing through a range of increasingly viscous consistencies using the International Dysphagia Diet Standardisation Initiative (IDDSI) framework.

Index test assessment: Cough Reflex Test (CRT)
CRT was administered using a Microneb 3 jet nebuliser (Clement Clarke International Limited, Essex, UK) with a restricted air flow rate of 6.6 litres per minute, following the protocol validated by Miles et al.'s 2013 study. We used a 0.6mol/L citric acid solution diluted with 0.9% sodium chloride, as per clinical use in the UK.

Gold standard assessment: Flexible Endoscopic Evaluation of Swallowing (FEES)
FEES was carried out using a standardised protocol. As per the CSE, FEES included the same trials of oral diet and fluids.

The outcome of each assessment was recorded before proceeding to the next. All assessments were carried out within 72 hours post-onset of stroke and were administered within 4 hours of each other. Participants were seated upright throughout.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The following variables will be assessed at one timepoint within 3 days of the onset of their stroke symptoms:
1. Observation of patients eating and drinking measured using the clinical swallowing examination (CSE)
2. Sensory and motor response of cough measured using cough reflex test (CRT)
3. Evaluation of swallowing measured using a fibreoptic endoscopic evaluation (FEES)

Key secondary outcome(s))
1. Percentage of eligible patients in this setting measured using the record of patients in the hyperacute stroke unit on each day of recruitment
2. Percentage of those eligible who consented to participate measured using patient study records at one timepoint
3. Demographics of eligible patients measured using patient study records at one timepoint
4. Duration of each test (CSE, CRT, FEES) measured using patient study records at one timepoint
5. Acceptability of FEES and CRT measured using a Likert scale) at one timepoint
6. Prevalence of silent aspiration by index tests (CSE, CRT) and the gold standard (FEES) measured using patient records; true and false positives, true and false negatives are recorded. Subsequently, statistics for diagnostic value are used to evaluate: sensitivity, specificity, positive and negative predictive values. These inform a preliminary assessment of likely diagnostic value and a power calculation for a larger study.

7. Power calculation predicated on diagnostic accuracy (overall agreement with gold standard test). McNemar’s Z-test was used to assess paired proportions; sample sizes were calculated using G-Power v3.1. measured from study results at one timepoint

Completion date
30/07/2021

Eligibility

Key inclusion criteria
1. Are admitted to the Royal Victoria Infirmary Hyper-Acute Stroke Unit (HASU) with a suspected or confirmed diagnosis of a new stroke
2. Are sufficiently alert to tolerate clinical swallow examination or cough reflex testing (i.e. able to maintain alertness for at least 20 minutes)
3. Have adequate head control and are able to tolerate being positioned upright for the duration of the assessment
Also:
4. Due to service restrictions, patients are required to have their swallowing assessment during working hours of Speech and Language Therapists carrying out cough reflex testing
5. Patients who are known to have high intracranial pressure will be discussed with the treating consultant prior to assessment as this is a potential contraindication for performing the test as per the protocol described by Miles and colleagues (2013)
6. Participants must have English as their primary language
7. Consent will be obtained prior to the assessment or the assessment will be completed in the participant's best interests if they are unable to consent (informed consent obtained)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Are under 18 years of age
2. Are medically deteriorating or being treated palliatively
3. Are too agitated to engage in assessment
4. Have a history of previous silent aspiration identified on instrumental swallow assessment
5. Are unable to provide informed consent to participate in the study and do not have an

appropriate spokesperson to provide consent on their behalf
6. Have a structural anomaly that could interfere with swallowing
7. Are more than 3 days post-stroke
8. COVID-19 suspected or confirmed

Date of first enrolment
30/10/2020

Date of final enrolment
20/07/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Newcastle upon Tyne Hospitals NHS Charity Bridging Stroke Fund

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mrs Julie Trimble, j.trimble@nhs.net. Case histories and study results will be anonymised. It will not be possible to link details from case histories or assessment findings to individual patients.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/05/2023	18/08/2023	Yes	No
Participant information sheet	version 1.1	24/08/2020	18/08/2023	No	Yes
Participant information sheet	version 1.1	10/08/2020	18/08/2023	No	Yes
Participant information sheet	version 1.1	24/08/2020	18/08/2023	No	Yes
Participant information sheet	version 1.1	24/08/2020	18/08/2023	No	Yes
Participant information sheet	version 1.1	24/08/2020	18/08/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes