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Screening for swallowing problems in patients admitted to Connaught Hospital with stroke: An early study to assess the practicalities of a proposed bigger study

Submission date
03/11/2021

Recruitment status
No longer recruiting

Registration date
14/02/2022

Overall study status
Completed

Last Edited
02/05/2023

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and aims
Stroke is a sudden medical condition that is very serious and can lead to death. Stroke can also cause a lot of problems. It is very important that these problems are found as quickly as possible to help patients get well and to stop them from becoming more ill.

Stroke can affect a person's ability to swallow food, water and medicines. Normally, food and water goes down the tube that connects a person's throat to their stomach. Stroke can cause food and water to go down the wrong tube and into the airways (aspiration). If food and fluids goes into the lungs, this can cause serious lung infection and the person to become very sick. It is important that we find out if a person has problems with food and water going into the airways and not the stomach. It is also important because if food and water goes down the wrong tube and into airways, then medicine given by mouth will also go into the airways. It is very important that we find people who have problems with food, water and medicines going into the airways as quickly as possible after they attend hospital with stroke. We do this to make sure that the person is given food, water and medicines in the correct way and in a way that will not cause harm.

We find people who have problems with food, water and medicines going into the airways (and not into the stomach) by using what is called a swallow screen. A swallow screen is a type of assessment designed to find people who have problems with food, water and medicines going into the airways.

We are introducing swallow screening into Connaught Hospital. We have chosen the Massachusetts General Hospital Swallow Screening Tool (MGH SST) and we have changed it in small ways to fit the Connaught Hospital setting. The MGH SST is used in hospitals in different countries across the world. It is a very good way of finding people with stroke who do and do not have trouble with food, water and medicines going into their airway. The swallow screen will be carried out by nurses who are specially trained.

The purpose of this small early stage study is to find out if we can deliver the nurse led swallow screen as conceived and planned within the current Connaught Hospital Stroke Pathway. We will use the information from this small study to help us design a bigger study which will help us answer important clinical questions.

Who can participate?
We are asking everyone who may have had a stroke, who comes to Connaught Hospital to take part. We are in contact with all hospital wards and departments where stroke patients might be seen. To take part people must be aged at least 18 years, have symptoms of acute stroke and have given informed consent.

What does the study involve?
If a person chooses to take part in the study, he or she will be asked to undergo a new nurse-led swallow screening assessment to find out if he or she has problems with food and water going down the wrong tube and into his or her airways and not into his or her stomach. This is called his or her 'risk for aspiration'.
First, the nurse will check that he or she is well enough to take food, water and medicine through his or her mouth. The nurse will do this by checking that he or she :
• can sit up to a 30 degree angle
• can stay awake for at least five minutes
• has stable breathing and good oxygen levels
• has a clean mouth

If the person is not well enough to take part, the nurse will assess him or her again with 24 hours. If the person is well enough to take part, then the nurse will ask him or her to carry out simple tasks and watch to see how well he or she manages. The tasks include:
• Stick out his or her tongue and lick all the way around his or her lips (to assess ability to move tongue)
• Cough (to assess a poor cough or unable to cough)
• Say 'ha, ha, ha, ha, ha' (to assess how good the voice is)

The nurse will then ask him or her to close his or her eyes and open mouth. The nurse will then touch the right and left wall of the throat one after another with cotton tipped swab. The nurse will then ask him or her to indicate what side of the throat wall has been touched.

How well he or she carries out each of these tasks gives the nurse information on whether he or she may or may not have problems with food, water or medicines going into his or her airways. For example, a strong cough is very important for protecting and clearing the airways if food, water or medication was to go down the wrong tube and into the airways. A poor or no cough shows that the airways cannot be protected or cleared and that he or she may be at risk.

Next, the nurse asks the person to take three single teaspoons of water and watches to see if he or she coughs, clears his or her throat, if there are voice changes or if there are any changes to his or her breathing. These are signs that the teaspoons of water have gone down the wrong tube into his or her airway. If the nurse sees any these signs the nurse will stop the assessment and re-screen the person within 24 hours. If there are no signs that the water has gone into his or her airway, the nurse will ask the person to drink ½ cup of water and watch to see if he or she coughs, clears his or her throat, if there are voice changes or changes to breathing. If the nurse sees any these signs the nurse will stop the assessment and re-screen the person within 24 hours.

The person is free to refuse to carry out any particular task if he or she does not wish to.

The nurse will tell the person the outcome of the swallow screen. The nurse will also tell the members of the clinical team and document the outcome in the medical and nursing notes.

What are the possible benefits and risks of participating?
We cannot promise the screening tool will help individual people/patients, but the information we get will help to improve care for people who have a stroke in the future. There are no known major risks in participating in the study.

Where is the study run from?
The College of Medicine and Allied Health Sciences (COMAHS), University of Sierra Leone, Freetown is Sierra Leone and School of Population Health & Environmental Sciences, King's Global Health Institute, King's College London, UK

When is the study starting and how long is it expected to run for?
April 2021 to March 2022

Who is funding the study?
This study was supported by the National Institute of Health Research (NIHR) Award ID: 17/63/66

Who is the main contact?
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Additional identifiers

Protocol serial number
SISLE 1, (NIHR) Award ID: 17/63/66

Study information

Scientific Title
Evaluation of a nurse-led swallow protocol in the Connaught Hospital Stroke Pathway: a non-randomised pilot study

Study objectives
The purpose of this feasibility work is to inform a randomised controlled trial (RCT) of a screening strategy to detect and manage aspiration risk. The aim is to investigate areas of uncertainty in advance of a later definitive RCT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 15/06/2021, King's College London BDM Research Ethics Subcommittee (Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London, SE1 9NH, UK; +44 (0) 2078484020; rec@kcl.ac.uk), ref: MOD-20/21-8467
2. Approved 17/06/2021, Office of the Sierra Leone Ethics and Scientific Review Committee (Directorate of Training and Research, 5th Floor, Youyi Building Brookfields, Freetown, Sierra Leone; no telephone number provided; efoday@health.gov.sl), ref: none provided

Primary study design
Observational

Study design
Prospective descriptive pilot study within a longitudinal hospital stroke-based registry

Study type(s)
Screening

Health condition(s) or problem(s) studied
Risk of aspiration in people who present to hospital with acute stroke

Interventions

Patient participants will undergo a new nurse-led swallow screening assessment that is designed to check that the participant is well enough to take food, water and medicine through his or her mouth. This will involve checking that the participant:
• Can sit up to a 30 degree angle
• Can stay awake for at least five minutes
• Has stable breathing and good oxygen levels
• Has a clean mouth
• Can stick out his or her tongue and lick all the way around his or her lips (to assess ability to move tongue)
• Can cough (to assess a poor cough or unable to cough)
• Can say 'ha, ha, ha, ha, ha' (to assess how good the voice is)
• Can identify which side of the inside of the throat has been touched with a cotton swab
• Can swallow 3 single teaspoons of water without aspiration of the water
• Can drink half a cup of water without aspiration of the water

If at any stage the patient is unable to complete the assessment without coughing or other symptoms of distress due to swallowing, the nurse will stop the assessment and re-screen the participant in 24 hours.

At the end of the study, interviews with study nurses and the volunteer speech and language therapist will be conducted to evaluate the components of the screening assessment.

Intervention Type
Behavioural

Primary outcome(s)
The number of completed screens for aspiration risk measured using case report forms at the end of the study

Key secondary outcome(s)
1. Door to screening time measured using patient notes and CRF at baseline
2. Time at potential risk for aspiration measured using CRFs at the end of the study
3. Time spent in each part (1 & 2) of the swallow protocol measured using CRFs at the end of the study
4. Fasting prior to screening measured using patient/caregiver interview and nurse interview at baseline
5. Frequency of enteral feeding prior to protocol administration measured using patient /caregiver interview and nurse interview at baseline
6. Occurrence of enteral feeding (ng tube) after administration of swallow protocol but prior to completion measured using CRFs at the end of the study
7. Frequency of deferred screen (part 1 and part 2) and reasons measured using CRFs at the end of the study
8. Frequency of screens administered and reasons measured using CRFs at the end of the study
9. Frequency of protocols not completed and reasons measured using CRFs at the end of the study
10. Average number of nurse contacts to complete part 'readiness to participate' (part 1) of screening form before patient moves on to part 2 measured using CRFs at the end of the study
11. Average length of time it takes to complete the swallow screening protocol from initial screen to final classification of aspiration risk measured using CRFs at the end of the study
12. Evaluation of individual swallow screening components measured using interviews with study nurses and the volunteer speech and language therapist at the end of the study

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. Adults ≥18 years
2. Ischaemic stroke
3. IntraCerebral Haemorrhage
4. Sub Arachnoid Haemorrhage

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. <18 years
2. No consent
3. Transient Ischaemic Attack (focal neurological signs recovering within 24 hours)
4. Known neurological disease with infectious aetiology

Date of first enrolment
07/09/2021

Date of final enrolment
05/10/2021

Locations

Countries of recruitment
Sierra Leone

Study participating centre
Connaught Hospital
Freetown
Sierra Leone
-

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

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

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 5		04/11/2021	No	Yes