ISRCTN11429329 https://doi.org/10.1186/ISRCTN11429329

Non-invasive swallow assessment device

Submission date
10/04/2025

Recruitment status
No longer recruiting

Registration date
11/06/2025

Overall study status
Ongoing

Last Edited
25/06/2025

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Swallowing difficulty, known as dysphagia, is a common medical condition that in some people may allow food or drink to pass into the airway, a process known as aspiration. Aspiration is more common in older patients and those with neurological disorders such as cerebral palsy, stroke or Parkinson's disease. Aspiration can lead to serious health complications such as pneumonia and may cause death.
This study aims to test a new device that may be able to detect aspiration without being invasive or using radiation like current diagnostic methods. The device is attached to the front of the neck to record sounds during swallowing. These sounds are then analysed by a computer to pick up features that suggest aspiration has occurred.
The study will test the device in patients already undergoing screening for aspiration using either x-rays (videofluoroscopy [VF]) or a flexible camera passed through the nose (flexible endoscopic evaluation of swallow [FEES]). The sounds recorded during swallowing by microphones in the device will be labelled as coming from a healthy or unhealthy swallow (e.g. aspiration) using the results of the VF or FEES tests. A computer will then develop an algorithm to assess these sounds in a way that picks out important differences that relate to swallow safety. The study team will determine if this algorithm could be used to predict whether a swallow is healthy or not based on what it sounds like. They will assess how accurately the algorithm can detect unhealthy swallows, to see if a bigger clinical trial should be conducted using the device. They will also collect feedback from patients and staff doing the testing to determine if the device is comfortable for patients and easy to use.

Who can participate?
Patients aged 16 years and over undergoing screening for aspiration at Cambridge University Hospitals

What does the study involve?
Before the investigation a member of the study team will explain the study and answer any questions. The potential participant will then be asked if they would like to take part in the study, and if so, they will be asked to give written permission (consent). Before a videofluoroscopy (x-ray) or FEES (camera) test, a member of the study team will attach a small device to the front of the participant's neck using medical double-sided tape and an elastic strap that goes around the neck and applies gentle pressure on the sensor. After this, the swallow investigation will be conducted as normal. At the end of the investigation the device will be

removed from the participant's neck, and they will be invited to provide feedback on the experience of wearing it. This will be the end of their involvement in the study.

What are the possible benefits and risks of participating?
There are no direct benefits associated with participating in this research. The device is non-invasive and has been approved as safe by the hospital engineering department. Occasionally individuals may find wearing the device uncomfortable. Very rarely, a component of the device may cause skin irritation or allergy. Those with known allergies to polythene or acrylate should not participate in the study. The study team will ensure that participation does not expose participants to any risk from additional swallow tests beyond those required for diagnosis, or to additional radiation exposure if the participant is having an x-ray test.

Where is the study run from?
The study is run from the Cambridge University Hospitals and the University of Cambridge (UK)

When is the study starting and how long is it expected to run for?
June 2022 to August 2025

Who is funding the study?
Medical Research Council (MRC) and the University of Cambridge (UK)

Who is the main contact?
Dr Matthew Smith, mes39@cam.ac.uk

Contact information

Type(s)

Contact name
Dr Maximilian Nussbaumer

ORCID ID
https://orcid.org/0000-0002-5686-1913

Contact details
Department of Engineering
University of Cambridge
Trumpington Street
Cambridge
United Kingdom
CB2 1PZ
+44 (0)7955 746974
mn406@cam.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

323842

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 57228, Grant Code: G116517

Study information

Scientific Title
Swallow assessment using a multi-channel non-invasive device: a feasibility study

Study objectives
This study aims to test a new device that may be able to detect aspiration without being invasive or using radiation like current diagnostic methods. The study is trialling a device that is attached to the front of the neck to record sounds during swallowing. These sounds are then analysed by a computer to pick up features that suggest aspiration has occurred.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/07/2023, London - Dulwich Research Ethics Committee (Health Research Authority, 2nd Floor, 2 Redman Place, Stratford, London, E20 1JO, UK; +44 (0)207 104 8290, +44 (0)207 104 8109; dulwich.rec@hra.nhs.uk), ref: 23/LO/0606

Study design
Non-randomized; Interventional; Design type: Diagnosis, Device

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Suspected dysphagia and/or aspiration

Interventions

Screening:
A member of the hospital clinical team will review the electronic medical record of patients attending routine and urgent videofluoroscopy (VF) or fibreoptic endoscopic evaluation of swallow (FEES) assessments. Participants screened will include all those in the VF or FEES clinic, and may be hospital inpatients or outpatients. Patients identified as potentially suitable for inclusion will then be highlighted to a study investigator for approach.

Approach:
The timing approach of patients that appear to meet the study criteria will depend on whether they are undergoing VF or FEES as an inpatient or as an outpatient investigation.
In most cases, inpatients will be first approached on the ward they are admitted to. This will occur in the days preceding their FEES or VF investigation, or on the morning of their investigation. Mealtimes and other busy periods will be avoided. All outpatients and some inpatients will be approached on their arrival in the waiting room, before their investigation.
In both cases, an investigator will introduce themselves and briefly outline the study and provide the paper Patient Information Sheet. After allowing time for the patient to read the information sheet, the investigator will confirm that the patient understands the process and purpose of the study and will invite any questions.

Consent:
If the investigator is satisfied that the patient meets study criteria, has the capacity to provide consent, and the patient would like to take part in the study, the investigator will gain written informed consent. For both inpatients and outpatients, this will be immediately prior to the investigation.

Swallow Assessment Device:
Once the participant has entered the room used for VF or FEES, there is normally a period while a speech and language therapist prepares the substances to be swallowed and readies the equipment. This time will be used for an investigator to fit the swallow assessment device to the participant's neck. The investigator will ensure the participant is comfortable and the device is secure to prevent the need for adjustment during clinical testing. The investigator will ask the participant to dry swallow (without food/water) a few times to check device position and ensure sound data recording is adequate.

Videofluoroscopy (VF):
VF will be performed according to local protocol, with investigations tailored to the patient’s symptoms and ability, and depending on their progress through the assessment. The assessment will be performed by an investigator who is a speech and language therapist and by an appropriately trained radiographer. No changes will be made to the VF investigation for the purposes of this study. During the course of VF, patients will typically be asked to swallow a range of consistencies and textures of foods. Most assessments will commence with the participant swallowing a small volume of dilute 'contrast', a substance that shows up on X-ray. At the end of the assessment, the device will be removed from the neck by an investigator. VF images will be anonymised and saved onto a password-protected USB memory stick for later analysis.

Fibreoptic Endoscopic Evaluation of Swallow (FEES):
FEES will be performed according to local protocol, with investigations tailored to the patient’s symptoms and ability, and their progress through the assessment. A similar range of consistencies may be assessed to VF, but typically milk or coloured food boluses may be trialled

as the test relies on visual assessment of swallow efficiency and safety. FEES images will be anonymised and saved onto a password-protected USB memory stick. At the end of the assessment, the device will be removed from the neck by an investigator.

Questionnaire:
A questionnaire will be given to patients after they complete their VF or FEES investigation. This will collect data on comfort and any concerns the patients had about the device or study procedures. In addition, the speech and language therapist and radiographer will be invited to comment on the impact, if any, of the device on the swallow assessment, and any potential improvements that could be made to the device or methodology.

Statistics and analysis:
After the FEES or VF examination, once the patient has left, the speech and language therapist will inspect the FEES video recording/VF video sequences and rate each swallow that was performed, providing the gold-standard reference diagnosis. The 8-Point Penetration-Aspiration Scale will be used to classify individual swallows as ‘Safe’, ‘Unsafe Penetration’ and ‘Aspiration’. Swallows will be marked in the sound data by correlating it with the FEES and VF recordings. Sound data for each swallow will be assessed with a variety of machine learning algorithms to see which is best at automatically identifying abnormal swallows. Once the algorithm has classed all recorded swallows as 'safe' or 'penetration/aspiration', we will determine the diagnostic accuracy of the device and algorithm as a way to assess swallow safety.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Swallow Assessment Device

Primary outcome measure
Device function in clinical practice determined using data quality and ease-of-use as markers at a single timepoint

Secondary outcome measures
Device diagnostic accuracy preliminary analysis using swallow acoustic data alongside videofluoroscopy and FEES-based diagnoses in patients with dysphagia at a single timepoint (sensitivity and specificity using videofluoroscopy as the gold standard, at a cohort and per patient level, using standard 2 x 2 tables)

Overall study start date
15/06/2022

Completion date
30/08/2025

Eligibility

Key inclusion criteria
1. Aged 16+ years
2. Undergoing videofluoroscopy or FEES for suspected dysphagia and/or aspiration
3. Capacity to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 27; UK Sample Size: 27

Key exclusion criteria
1. Tracheostomy in place or previous tracheostomy
2. Active or previously treated cancer of the aerodigestive tract in the head and neck (i.e., not including local thyroid, salivary and skin malignancy)
3. Loss of skin integrity over front of neck
4. Contact sensitivity or allergy to any external component of the worn device

Date of first enrolment
09/11/2023

Date of final enrolment
25/06/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road

Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

Sponsor details
Cambridge Biomedical Campus
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ
+44 (0)1223348494
cuh.research@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/

ROR
https://ror.org/04v54gj93

Organisation
University of Cambridge

Sponsor details
The Old Schools
Trinity Lane
Cambridge
England
United Kingdom
CB2 1TN
+44 (0)1223 337733
croenquiries@admin.cam.ac.uk

Sponsor type
University/education

Website

http://www.cam.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
University of Cambridge

Results and Publications

Publication and dissemination plan
A lay summary of results will be made available to patient groups that have been involved in the study to date. Public dissemination of results will depend on the status of intellectual property, and could represent a limited disclosure of results or, if appropriate, publication in a high-impact peer-reviewed journal.

Intention to publish date
30/08/2026

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