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Comparing virtual assessment of the airway to in-person assessment

Submission date 20/04/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/04/2021	**Overall study status** Completed	
Last Edited 04/05/2021	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Patients that are due to undergo an operation that requires general anaesthesia, attend a pre-operative assessment clinic. This allows for patient information to be gathered, in order to help anticipate any potential problems or delays. One area of assessment is a simple anatomical and functional assessment of the patient's airway. This is designed to help identify patients that might have an airway that is difficult for anaesthetists to insert a breathing tube into. The SARS-CoV-2 outbreak resulted in many face-to-face services moving to a virtual service provision model. Virtual anaesthetic pre-operative assessment has the potential to impact on the opportunities for, and accuracy of, airway assessment. It is not known if virtual airway assessment correlates with face-to-face assessment.

This study aims to compare virtual assessment of the airway with that of traditional in-person anaesthetic assessment by collecting basic demographic data and data relating to airway anatomical assessment of adults over the age of 18, before they undergo an operation under general anaesthesia. Additionally, the study also aims to determine how often video assessment is unacceptable, what factors make the assessment unacceptable, and what recommendations can be drawn from these findings to optimise the assessment.

Who can participate?
Adult patients due to undergo an operation under general anaesthesia

What does the study involve?
Data will be collected at two points during the participants' involvement with the study. The initial remote video airway assessment will be carried out by a member of the pre-operative assessment clinic. The second data collection point will occur when the participant attends for their operation under general anaesthesia. The data will then be compared to determine the level of agreement between raters, which assessments can be performed adequately virtually and what are the common problems that prevent accurate measurement.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in the study, but participants will be helping to improve the understanding of how comparable video airway assessment is to face-to-face assessment, and what can be done to improve the assessment.

There are no specific risks to participants health or wellbeing as the only change will be to collect more information regarding their airway assessment. Data will be collected and stored following strict security and confidentiality guidelines that include anonymising data, encrypting data and limiting access to select members of the research team.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
From January 2021 to May 2022

Who is funding the study?
Great Western Hospital Academy (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
294205

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 294205

Study information

Scientific Title
Anaesthetic pre-operative Assessment of the adult Airway and Non-Specialist video Assessment (AAANSA): a method-comparison study

Acronym
AAANSA

Study objectives
To determine if the findings from the remote video non-specialist airway assessment correlate with the results of an in-person anaesthetic assessment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/04/2021, South Central - Oxford A Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol BS1 6PN; +44 (0)207 104 8284, +44 (0)207 104 8206, +44 (0)207 104 8048; oxforda.rec@hra.nhs.uk), ref: 21/SC/0120

Study design
Single centre method-comparison study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Airway assessment in adults undergoing elective surgery

Interventions
The study will involve the collection of the patient's airway data via two separate methods and comparing the results. Healthcare professionals working within the pre-operative assessment clinic are already completing remote video assessments of the airway. As part of the study, they will collect additional data on airway assessment tests and anatomical markers. The healthcare professional conducting the assessment will also be asked to record any technical problems or limitations that impeded their assessment of the airway.

The participants will then undergo a second identical airway assessment, in-person, by an anaesthetist, on the day of their surgery. A comparison between the results of the two airway assessments made by the non-specialist and the anaesthesiologist will be conducted on each of the airway measurements using kappa analysis.

Intervention Type
Other

Primary outcome(s)
Level of agreement between two or more raters for assessment of the adult airway when assessed virtually at pre-operative assessment and in-person on the day of surgery

Key secondary outcome(s))
1. Elements of pre-operative airway assessment which can be adequately assessed remotely measured by comparison of data collected during virtual airway assessment at pre-operative assessment and in-person airway assessment on the day of surgery
2. Identification of how the quality of remote video airway assessment can be optimised measured by comparison of data collected during virtual airway assessment at pre-operative assessment and in-person airway assessment on the day of surgery

Completion date
01/05/2022

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Attending a pre-operative remote video assessment clinic prior to an operation under general anaesthesia
3. Access to a mobile phone device with the ability to video call

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Lacking capacity to give consent
2. Unwilling to give consent
3. Pregnancy
4. Prisoners
5. Prior participation in the study
6. Does not speak English
7. Difficultly understanding verbal or written instructions

Date of first enrolment
03/05/2021

Date of final enrolment
22/04/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Great Western Hospital
Marlborough Road
Swindon
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Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Great Western Hospital Academy

Results and Publications

Individual participant data (IPD) sharing plan
The anonymised final dataset will be available via the Bristol Research Data Repository (https://data.bris.ac.uk/data/). The full (anonymised) participant data set and individual participant data will be available. The data will be published under open access via the University of Bristol Research Data Repository for any purpose. The data will be submitted within one year of the study end date (before 01/05/2023) and will be available for 10 years from publication data. Additional documents such as the Protocol, Consent form and IRAS submission will happily be provided on request.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version v1.1	19/04/2021	04/05/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v1.1	19/04/2021	04/05/2021	No	No