

Studying aerosol emission of the COVID-19 virus in healthcare settings

Submission date 01/10/2020	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/10/2020	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/12/2021	Condition category Infections and Infestations	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Aerosol generation occurs when tiny droplets of liquid are suspended in the air. Aerosols can be generated during many medical procedures. Some procedures might produce more aerosols than others, and droplets of different sizes, but this is largely unknown at the moment. However, aerosols can carry viruses, like coronavirus, which risks further infections if inhaled by healthcare staff or other patients. This study aims to determine how aerosol is produced in healthcare settings and how it settles and disperses. This is critical, as it is increasingly recognised that COVID-19 can spread via aerosol. Many healthcare procedures (such as intubation) are considered potentially 'aerosol-generating', which means healthcare workers have to wear personal protective equipment (PPE) and there are delays in procedures. This study aims to measure whether and how much aerosol is actually generated in these procedures, how long it takes to settle, and whether it is possible to mitigate the risk of aerosol spread in hospitals. This will aim to inform whether the PPE worn during these procedures is correct, and what can be done to try and limit risk to staff and patients of aerosol transmission of coronavirus. This study will be performed in hospitals, specifically at North Bristol NHS Trust and University Hospital Bristol and Weston NHS Foundation trust, using equipment from the School of Chemistry at the Bristol Aerosol Research Centre to measure aerosol.

Who can participate?

People will be recruited from two sources: patients who are undergoing procedures as part of routine care in hospitals already, and healthy volunteers. Healthy volunteers must be adults (>18) and must not have COVID-19 symptoms.

What does the study involve?

The study involves measurement of aerosol using small machines, about the size of a computer, attached to funnels that will measure aerosol in the air near participants. Routine data such as age, sex, and BMI will be recorded. No follow up will be arranged, and no other medical procedures will be performed.

What are the possible benefits and risks of participating?

There are no potential benefits of entering, apart from helping the researchers. There are no anticipated negative effects or side effects.

Where is the study run from?

The study is a collaboration between North Bristol NHS Trust, the University of Bristol, and University Hospital Bristol and Weston NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

September 2020 to September 2021

Who is funding the study?

National Institute for Health Research and the UK Research Institutes (NIHR-UKRI) (UK)

Who is the main contact?

Fergus Hamilton

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Contact information

Type(s)

Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
288784

Central Portfolio Management System (CPMS)
47097

Protocol serial number
3.4

Study information

Scientific Title
AERosolisation And Transmission Of SARS-CoV-2 in Healthcare Settings (AERATOR)

Acronym
AERATOR

Study objectives
The aim of this study is to quantify the flux, concentration, size distribution, and persistence of aerosol generated by a diverse set of clinical procedures across various settings, and assess heterogeneity between operator, equipment, and room.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/09/2020, North West Greater Manchester Central REC (Third Floor, Barlow House, Minshull Street, M1 3DZ, UK; +44 (0)207 104 8193, +44 (0)207 104 8007, +44 (0)207 104 8208; gmcentral.rec@hra.nhs.uk), REC ref: 20/NW/0393

Primary study design
Observational

Study design
Aerosol and environmental sampling study

Study type(s)
Other

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions

The AERATOR study will be carried out using specialist equipment in operating theatres and wards to measure real-life aerosol generation in five clinical settings: dental, orthopaedic, respiratory, critical care and ophthalmology. By using specialist equipment, only available at the University of Bristol, the research team will also investigate how long coronavirus survives while airborne and how environmental conditions impact on the infectivity of the virus.

The research will also advise guidelines on the appropriate level of PPE for staff, as well as the length of time the aerosol is present for and how it spreads in a real-world clinical setting.

The total duration of observation for each participant is around 15 minutes to 1 hour. The trial will run for 1 year.

Intervention Type

Device

Phase

Not Applicable

Primary outcome(s)

1. Distribution of aerosol produced during routine or simulated procedures measured using Aerodynamic Particle Sensors during the procedure, and for up to 10 minutes after
2. Distribution of aerosol produced during routine or simulated procedures measured using Optical Particle Sensors during the procedure, and for up to 10 minutes after

Key secondary outcome(s)

Distribution of aerosol produced and dissemination measured with Aerodynamic and Optical Particle sensors across a clinical room during procedures and for up to 1 hour after

Completion date

19/09/2021

Eligibility

Key inclusion criteria

Patients:

1. Undergoing procedure that is potentially aerosol-generating
2. Aged over 18
3. Have capacity

Healthy volunteers:

1. Have capacity to consent to the study
2. Aged over 18

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Patients:

1. Unable to read/understand PIS (either printed version or via translator)
2. Unable to consent

Healthy volunteers:

1. Flu-like symptoms (fevers, temperature, new cough, sore throat, loss of smell, breathing difficulties) in the 48 hours prior to study enrolment
2. Clinical contraindication to the procedure being performed

Date of first enrolment

19/09/2020

Date of final enrolment

19/09/2021

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

North Bristol NHS Trust

Southmead Hospital

Southmead Road

Westbury-on-Trym

Bristol

United Kingdom

BS10 5NB

Study participating centre

University Hospitals Bristol and Weston NHS Foundation Trust

Upper Maudlin Street, Bristol

Bristol

United Kingdom

BS2 8HW

Sponsor information

Organisation

North Bristol NHS Trust

ROR

<https://ror.org/036x6gt55>

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

Funder Name

UK Research and Innovation

Results and Publications

Individual participant data (IPD) sharing plan

Trial-level data will be held at the Bristol Aerosol Research Centre, as this will simply be aerosol measurements attached to the age, sex, and BMI. The researchers are unable to share patient-level data due to sponsor-level agreements around sharing trial data. Interested parties can contact Fergus Hamilton (fergus.hamilton@bristol.ac.uk) to discuss further.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	manual facemask ventilation quantitative evaluation	26/10/2021	27/10/2021	Yes	No
HRA research summary			28/06/2023	No	No
Preprint results	non-peer-reviewed aerosol emission results in preprint	01/02/2021	19/03/2021	No	No
Preprint results	tracheal intubation and extubation sequences quantitative evaluation in preprint	14/12/2021	16/12/2021	No	No