

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

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
01/10/2020	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
16/10/2020	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
16/12/2021	Infections and Infestations	

## 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

[fergus.hamilton@nbt.nhs.uk](mailto:fergus.hamilton@nbt.nhs.uk)

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Fergus Hamilton

**ORCID ID**

<https://orcid.org/0000-0002-9760-4059>

**Contact details**

Infection Science

Pathology Services

Southmead Hospital

Bristol

United Kingdom

BS10 5NB

+44 (0)7743165499

[fergus.hamilton@nbt.nhs.uk](mailto:fergus.hamilton@nbt.nhs.uk)

**Type(s)**

Public

**Contact name**

Dr Fergus Hamilton

**ORCID ID**

<https://orcid.org/0000-0002-9760-4059>

**Contact details**

Infection Science

Pathology Services

Southmead Hospital

Bristol

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BS10 5NB  
+44 (0)07743165499  
fergus.hamilton@nbt.nhs.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

288784

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

3.4, IRAS 288784, CPMS 47097

## 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

### Study design

Aerosol and environmental sampling study

### Primary study design

Observational

### 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](mailto: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?
<a href="#">Results article</a>	manual facemask ventilation quantitative evaluation	26/10/2021	27/10/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Preprint results</a>	non-peer-reviewed aerosol emission results in preprint	01/02/2021	19/03/2021	No	No
<a href="#">Preprint results</a>	tracheal intubation and extubation sequences quantitative evaluation in preprint	14/12/2021	16/12/2021	No	No