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

Submission date
01/10/2020

Recruitment status
No longer recruiting

Registration date
16/10/2020

Overall study status
Completed

Last Edited
16/12/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 settles, 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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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
288784

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Aerosol and environmental sampling study

Study setting(s)
Hospital

Study type(s)
Other

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

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 measure
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

Secondary outcome measures
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

Overall study start date
19/09/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

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
England

United Kingdom

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

Sponsor details
Learning and Research Building
Level 3
Southmead Hospital
Bristol
England
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BS10 5NB
+44 (0)117950505
researchsponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. All articles will be disseminated rapidly to key stakeholders, and where possible, via pre-print servers.

Intention to publish date
01/01/2021

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?
Preprint results	non-peer-reviewed aerosol emission results in preprint	01/02/2021	19/03/2021	No	No
Results article	manual facemask ventilation quantitative evaluation	26/10/2021	27/10/2021	Yes	No

Preprint results	tracheal intubation and extubation sequences quantitative evaluation in preprint	14/12/2021	16/12/2021	No	No
HRA research summary			28/06/2023	No	No