ISRCTN10378358 https://doi.org/10.1186/ISRCTN10378358

Reducing the risk of COVID-19 spread in hospitals, by stopping droplets from spreading

Submission date	Recruitment status	[X] Prospectively registered
13/06/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/07/2020	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/03/2022	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Aerosol Generating Procedures – are a group of procedures that splatter drops into the hospital environment, these droplets can carry COVID-19 in infected patients. Because of this they have been regulated by the NHS, however there is little real data about them. This trial aims to image the droplet and aerosol formation from AGPs and to measure the effect of a simple barrier placed over the AGP, to see whether this reduces the spread of droplets into the hospital environment. If we can prove this to be the case, the NHS will benefit by being able to work in a more efficient / normal manner.
This trial is looking at reducing the effect of Aerosol generating procedures, by draping the patient in a plastic sheet.

Who can participate?
Patients undergoing AGP at Queen Alexandra Hospital and patients in the dental faculty of University of Portsmouth aged 18 years or above.

What does the study involve?
The study involves placing a clear plastic drape over the AGP, and measuring the spread of droplets. Some patients will be randomised to receiving this drape and others will simply have their normal treatment. We will ensure that any drape does not affect the normal care that the patient receives. We will be using a fluorescein dye with special lights and cameras to capture images of the droplets spread from patients undergoing AGPs. We hope to show that simple measures such as using a physical barrier can help in the prevention of spread of these droplets and therefore COVID-19 in hospital.

What are the possible benefits and risks of participating?
The potential benefits are huge for the NHS, if we can get back to working normally and efficiently the individual patients may receive better care and their friends and family too.

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

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

Who is funding the study?
UK Research and Innovation

Who is the main contact?
Prof. Richard Newsom, richard.newsom@port.ac.uk

Contact information

Type(s)
Public

Contact name
Prof Richard Newsom

ORCID ID
https://orcid.org/0000-0002-2221-0653

Contact details
Faculty of Science and Health
St. Michael's Building
White Swan Road
Portsmouth
United Kingdom
PO1 2DT
+44 (0)23 9284 2994
richard.newsom@port.ac.uk

Type(s)
Scientific

Contact name
Prof Richard Newsom

ORCID ID
https://orcid.org/0000-0002-2221-0653

Contact details
Faculty of Science and Health
White Swan Road
Porstmouth
United Kingdom
PO1 2DT
+44 (0)23 9284 2994
richard.newsom@port.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
285515

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 285515

Study information

Scientific Title
Oral fluorescein as a biomarker for droplet and aerosol spread of COVID-19 within a clinical environment

Study objectives
We propose to measure the spread of droplets within high risk clinical procedures called Aerosol Generating Procedures (AGPs). We will measure the droplets and aerosols produced by patients under going treatment and see if we can reduce them with a simple plastic sheet. We will also measure droplet spread on the ward and outpatients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not provided at time of registration

Health condition(s) or problem(s) studied
Patients undergoing AGP

Interventions

The researchers will stain the saliva and nasal secretions with Fluorescein 2%, one drop in the mouth and one in each nostril. The AGP will be performed and the spread of the droplets will be gathered from screens set at 1 m distant. These will be angled vertical and horizontal at a height of 1.0m, the aim being to catch a sample of the falling droplets. These will be imaged with hyperspectral and forensic photography but also microscopy to detect minute droplet particles.

For each AGP we will measure 30 patients, randomised into two groups: those with no plastic covering and those with a plastic covering with a drape. The dental patients will be randomised to having a dental rubber dam vs no rubber dam.

AGPs
1. Intubation and extubating
2. Tracheostomy (insertion or open suction or removal)
3. Bronchoscopy and upper airway procedures
4. Upper gastrointestinal endoscopy
5. Cataract surgery – involving phaco probe
6. Dental procedures involving high-speed drilling/hygiene
7. Non-invasive ventilation e.g. Continuous positive pressure ventilation
8. Induction of sputum
9. High flow nasal oxygen

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Plastic sheet 2 x 3 m

Primary outcome measure
The proportion of patients where the spread of airborne droplets during AGP is > 50 drops on a detection pad at 1 m

Secondary outcome measures
none

Overall study start date
15/06/2020

Completion date
01/03/2022

Eligibility

Key inclusion criteria
1. Patients undergoing AGP at Queen Alexandra Hospital
2. Patients in dental faculty University of Portsmouth
3. Aged 18 years or above

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Not able to consent to the investigation
2. COVID-19 infection, or symptoms
3. Allergy to fluorescein, or multiple allergies

Date of first enrolment
01/11/2020

Date of final enrolment
01/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Alexandra Hospital
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
University of Portsmouth
Winston Churchill Avenue
Portsmouth
United Kingdom
PO1 2UP

Sponsor information

Organisation
University of Portsmouth

Sponsor details
University House
Winston Churchill Avenue
Portsmouth
United Kingdom
P01 2UP
-
simon.kolstoe@port.ac.uk

Sponsor type
University/education

Website
https://www.port.ac.uk/about-us/contact-us

ROR
https://ror.org/03ykbk197

Organisation
Queen Alexandra Hospital

Sponsor details
Cosham
Portsmouth
England
United Kingdom
PO6 3LY
+44 (0)23 9228 6000
Alice.Mortlock@porthosp.nhs.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/04rha3g10

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Request to richard.newsom@port.ac.uk – from website: https://researchportal.port.ac.uk/portal/ - for ten years – no personal patient data will be retained, but consent will be taken.

IPD sharing plan summary
Available on request