

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

Submission date 13/06/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/07/2020	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/03/2022	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
Portsmouth
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