

# Investigating blood clotting changes in patients with COVID-19

<b>Submission date</b> 11/05/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/05/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/07/2021	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Infection rates with COVID-19 have risen rapidly across the UK. In patients admitted to hospital with this infection, doctors are noticing unusual abnormalities in blood test results, especially those that measure blood clotting. This is particularly marked in patients with the most severe COVID-19 infection who need to be put on a ventilator in an intensive care unit (ICU). Early studies from China and other European countries also highlighted these clotting abnormalities. It seems that small clots develop in the lungs and sometimes in the kidneys and this can cause these organs to fail. Larger clots can also develop, such as those found in the large blood vessels of the lung (pulmonary emboli, PE) and legs (deep vein thrombosis, DVT). The pattern of clots seen with COVID-19 infection is highly unusual and needs further investigation.

The researchers would like to study the changes to clotting tests (and other blood tests) in all patients admitted to hospital with COVID-19, and to compare the test results seen in patients who require intensive care treatment to those with milder illness. They are particularly interested in whether patients with COVID-19 infection have a higher than normal risk of developing blood clots (both large and small types of clot). The results will be used to understand whether basic blood tests can predict the likelihood that a patient will require intensive care or that they will develop small clots and/or large clots. The tests also might predict the likelihood that a patient with COVID-19 will develop a blood clot while in hospital or after being sent home and whether treatments that have been given as routine care are associated with a reduced risk of clots. Overall, the researchers aim to use these results to understand whether there should be new clot prevention strategies (e.g. higher doses of clot prevention treatments) for all or some of patients with COVID-19.

### Who can participate?

Adults admitted to Oxford hospitals with COVID-19

### What does the study involve?

This is an observational study, which means that all participants will receive treatment and care as usual. Additional information will be collected on blood clotting and whether participants experience problems related to blood clots while in hospital and in the 90 days after they have been discharged from hospital.

What are the possible benefits and risks of participating?  
All participants will receive treatment and care as usual. There are no additional risks of participating.

Where is the study run from?  
Oxford University Hospitals NHS Trust

When is the study starting and how long is it expected to run for?  
March 2020 to November 2020

Who is funding the study?  
The investigators are funding the study.

Who is the main contact?  
Dr Nicola Curry, [haemophilia.reception@ouh.nhs.uk](mailto:haemophilia.reception@ouh.nhs.uk)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**  
282457

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**

## Study information

### Scientific Title

An observational study to evaluate the haematological changes caused by COVID-19 and their association with thrombotic clinical outcomes

### Study objectives

To describe the prevalence and longitudinal changes to coagulation, platelet and haematological parameters in patients with COVID-19 who present for emergency assessment and may require admission to adult critical and other wards and their relationship to routine blood tests.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 06/05/2020, London - London Bridge Research Ethics Committee (Skipton House, 80 London Road, London SE1 6LH; +44 (0)207 104 8029; londonbridge.rec@hra.nhs.uk), ref: 20/HRA/2304

### Study design

Observational study

### Primary study design

Observational

### Secondary study design

Cohort study

### Study setting(s)

Hospital

### Study type(s)

Other

### Participant information sheet

No participant information sheet available.

### Health condition(s) or problem(s) studied

Thrombosis in patients with COVID-19 (SARS-CoV-2 infection)

### Interventions

This observational study will collate data on the longitudinal changes seen in clotting test results and correlate these with clinical thrombotic outcomes. It will focus on the rates of venous and arterial thrombosis seen during in-patient stays and will also collect data around venous thrombosis occurring in the 90 days following patient discharge. These data will provide high quality data around the incidence of thrombosis in this patient group and will inform practice change for VTE prevention.

## **Intervention Type**

Other

### **Primary outcome measure**

1. Coagulation parameters (PT, aPTT, fibrinogen, D-dimer) measured using standard hospital laboratory methods in blood taken on days 1, 2, 3, 7, 14, 21 and 28 during hospital stay
2. Blood clotting capability measured by thromboelastography (TEG) using a TEG 5000 machine in whole blood taken on days 1, 2, 3, 7, 14, 21 and 28 during hospital stay
3. Full blood count (FBC) results (platelet count, haemoglobin, white cell count [WCC] and differential) measured using standard hospital laboratory methods in blood taken on days 1, 2, 3, 7, 14, 21 and 28 during hospital stay
4. Presence of venous thrombosis defined as radiological confirmed evidence of DVT by compression ultrasound or PE by CT pulmonary angiogram (CTPA) or ventilation/perfusion (VQ) scan from date of admission to 90 days following discharge
5. Presence of arterial thrombosis defined as ECG evidence of a myocardial infarction or CT/MRI evidence of an ischaemic stroke during hospital admission

### **Secondary outcome measures**

1. Aspartate transaminase (AST) measured using standard hospital laboratory methods in blood taken on days 1, 2, 3, 7, 14, 21 and 28 during hospital stay
2. Ferritin measured using standard hospital laboratory methods in blood taken on days 1, 2, 3, 7, 14, 21 and 28 during hospital stay
3. Troponin measured using standard hospital laboratory methods in blood taken on days 1, 2, 3, 7, 14, 21 and 28 during hospital stay
4. C-reactive protein (CRP) measured using standard hospital laboratory methods in blood taken on days 1, 2, 3, 7, 14, 21 and 28 during hospital stay
5. Bilirubin measured using standard hospital laboratory methods in blood taken on days 1, 2, 3, 7, 14, 21 and 28 during hospital stay
6. Lactate dehydrogenase (LDH) measured using standard hospital laboratory methods in blood taken on days 1, 2, 3, 7, 14, 21 and 28 during hospital stay
7. Co-morbid conditions assessed using patient electronic medical records from admission data
8. Transfusion need assessed using patient electronic medical records during the in-patient stay
9. ISTH bleeding score assessed using using patient electronic medical records during the in-patient stay
10. Presence of multiple organ failure (MOF) assessed using using patient electronic medical records during the in-patient stay
11. Presence of acute respiratory distress syndrome (ARDS) assessed using using patient electronic medical records during the in-patient stay
12. Presence of acute kidney injury (AKI) assessed using using patient electronic medical records during the in-patient stay
13. Organ failure assessed using sequential organ failure assessment (SOFA) score during the in-patient stay
14. Mortality assessed using patient electronic medical records during the in-patient stay
15. VTE assessed using patient electronic medical records and the hospital acquired thrombosis alert system, already in place for recording this data, up to 90 days post-hospital discharge

### **Overall study start date**

01/03/2020

### **Completion date**

30/11/2020

# Eligibility

## Key inclusion criteria

1. Adult (aged 18 years or older)
2. Admitted to Oxford University Hospitals NHS Foundation Trust with confirmed or high clinical suspicion of COVID-19

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

All adult patients admitted to Oxford hospitals between the dates 1st March 2020 and 31st August 2020 with COVID-19 infection

## Total final enrolment

303

## Key exclusion criteria

Does not meet inclusion criteria

## Date of first enrolment

01/03/2020

## Date of final enrolment

31/08/2020

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

Oxford University Hospitals NHS Foundation Trust  
Headley Way  
Oxford  
United Kingdom  
OX3 9DU

# Sponsor information

## Organisation

Oxford University Hospitals NHS Trust

## Sponsor details

Research and Development  
Joint Research Office  
Second Floor  
OUH Cowley  
Unipart House  
Garsington Road  
Oxford  
England  
United Kingdom  
OX4 2PG  
+44 (0)1865 572970  
ouh.sponsorship@ouh.nhs.uk

## Sponsor type

Hospital/treatment centre

## Website

<http://www.ouh.nhs.uk/>

## ROR

<https://ror.org/03h2bh287>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

The investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authorship for any publications

arising from this study will follow the rules set out by the International Committee of Medical Journal Editors definitions of Authorship and Contributorship, [http://www.icmje.org/ethical\\_1author.html](http://www.icmje.org/ethical_1author.html).

### **Intention to publish date**

01/01/2021

### **Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

### **IPD sharing plan summary**

Other

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		22/12/2020	13/07/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No