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Does point-of-care testing for coronavirus in hospital improve patient care compared to laboratory testing?

Submission date
17/03/2020

Recruitment status
No longer recruiting

Registration date
18/03/2020

Overall study status
Completed

Last Edited
08/04/2024

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
COVID-19 is caused by a virus that infects the respiratory tract of people and makes them unwell. It started in a city in China and has now spread to several other countries around the world, including the United Kingdom. There is no vaccine or treatment for COVID-19 at the moment and governments are trying hard to stop it from spreading by making sure that infected people are identified as soon as possible and kept away from others. To know who has the infection you need to do a test and at the moment this is done in large laboratories within hospitals. Although laboratory testing is accurate, it takes a long time to get results back, leading to long delays in identifying positive cases and in identifying patients who are negative. Companies have developed tests for COVID-19 that can be performed outside of the laboratory and take just one hour to give a result. Having a rapid test result may allow doctors to identify infected patients much more rapidly and to stop the virus from spreading in hospitals. It may also identify those who are not infected much earlier allowing them to be taken out of isolation rooms earlier and sent home quickly, easing pressure on the NHS. Previous studies showed that rapidly testing for viruses close to the patient, rather than in laboratories, leads to improvement in patient care. The aim of this study is to find out whether using a new rapid test for COVID-19 performed near the patient leads to earlier decision making and better care for patients.

Who can participate?
Patients aged 18 and over with suspected COVID-19

What does the study involve?
Patients will have a nose and throat swab collected and tested immediately using the new rapid test (QIAstat-Dx Respiratory n-CoV Panel). Results are available in 1 hour and will be communicated immediately to clinical and infection control teams. There is no patient follow up but clinical outcome data are collected retrospectively from case notes for the duration of hospitalisation, up to 30 days later.

What are the possible benefits and risks of participating?
The potential benefits of the new test are having a rapid result for Covid-19 and other infections

which may improve clinical management including the rapid and appropriate use of isolation facilities. Beyond the mild discomfort of having upper respiratory swabs and blood taken, there are not expected to be any significant risks from participating.

Where is the study run from?
Southampton General Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2020 to April 2021

Who is funding the study?
University Hospital Southampton NHS Foundation Trust (UK)

Who is the main contact?
Dr Tristan Clark
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Contact information

Type(s)
Scientific

Contact name
Dr Tristan Clark

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
280621

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RHM MED1696, IRAS 280621

Study information

Scientific Title
Evaluating the clinical impact of routine molecular point-of-care testing for COVID-19 in adults presenting to hospital: A prospective, interventional, non-randomised, controlled study (CoV-19POC)

Acronym
CoV-19POC

Study objectives
Routine molecular point-of-care testing for COVID-19 will reduce the time to results and improve the clinical management of patients presenting to hospital with acute respiratory illness, compared to the reference standard of laboratory RT-PCR testing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/03/2020, Substantial Amendment 1 approved 23/06/2020, South Central - Hampshire A Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8033, hampshirea.rec@hra.nhs.uk), ref: 20/SC/0138

Study design
Prospective interventional non-randomized controlled study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Patients will have a nose and throat swab collected and tested immediately using the QIAstat-Dx Respiratory n-CoV Panel. Results are available in 1 hour and will be communicated immediately to clinical and infection control teams. There is no patient follow up but clinical outcome data are collected retrospectively from case notes and hospital information systems for the duration of hospitalisation, up to 30 days post-intervention.

Added 21/07/2020:
Participant allocation: during periods when point-of-care testing was operational, potential patient-participants were approached for recruitment into the intervention; patients tested in the same time period by the local laboratory by RT-PCR were assessed for eligibility for entering the control group.

Intervention Type
Other

Primary outcome(s)

Time from COVID-19 test being requested to the result being available to clinical teams in minutes and hours, recorded during hospitalisation

Key secondary outcome(s))

Current secondary outcome measures as of 20/07/2020:
Measured using retrospective analysis of case notes and hospital information systems and unless specified otherwise measured for the duration of hospitalisation or up to 30 days, whichever is shorter:
1. The time from presentation to hospital to COVID-19 test result
2. Time spent in COVID-19 assessment cohort area
3. Time to definitive ward move
4. Number of bed moves
5. Duration of hospitalisation
6. Number and proportion of clinically unsuspected COVID-19 positive patients detected
7. Proportion of patients treated with antibiotics
8. Proportion of patients treated with single doses or brief courses (<48 hours) of antibiotics
9. Duration of antibiotic use, days
10. Proportion of all influenza antiviral use occurring in influenza-positive patients
11. Proportion of all influenza antiviral use occurring in influenza-negative patients
12. Time from admission to influenza antiviral commencement
13. Duration of influenza antiviral use, days and doses
14. Proportion of patients with ICU or RHDU admission
15. Proportion readmitted to hospital within 30 days
16. In-hospital, 30- and 60-day mortality
17. Reliability (proportion of run failures), ease-of-use scores, and implementation feasibility assessment (narrative) of QIAstat-Dx Respiratory SARS-CoV-2 Panel, used at the point-of-care
18. Sensitivity, specificity, positive predicted value, negative predictive value, percentage positive agreement, percentage negative agreement, percentage overall agreement, and overall diagnostic accuracy of QIAstat-Dx SARS-CoV-2 assay (as part of QIAstat-Dx Respiratory SARS-CoV-2 Panel) compared to laboratory PCR using the PHE RdRP assay

Previous secondary outcome measures:
Measured using retrospective analysis of case notes and hospital information systems and unless specified otherwise measured for the duration of hospitalisation or up to 30 days, whichever is shorter:
1. The time from presentation to hospital to COVID-19 test result
2. Time from admission to isolation of COVID-19 positive cases
3. Time from admission to de-isolation of COVID-19 negative patients
4. Duration of isolation facility use
5. Duration of negative-pressure isolation facility use
6. Duration of hospitalisation
7. Number and proportion of clinically unsuspected COVID-19 positive patients detected
8. Proportion of patients treated with antibiotics
9. Proportion of patients treated with single doses or brief courses (<48 hours) of antibiotics
10. Duration of antibiotic use, days
11. Proportion of all influenza antiviral use occurring in influenza-positive patients
12. Proportion of all influenza antiviral use occurring in influenza-negative patients
13. Time from admission to influenza antiviral commencement
14. Duration of influenza antiviral use, days and doses
15. Time from admission to isolation of influenza-positive cases, hours
16. Time from admission to de-isolation of influenza negative cases, hours

17. Proportion of patients with ICU or RHDU admission
18. Proportion readmitted to hospital within 30 days
19. In hospital, 30 and 60 day mortality
20. Reliability (proportion of run failures), ease-of-use scores, and implementation feasibility assessment (narrative) of QiAstat-21. Dx Respiratory Panel Plus, used at the point of care
22. Sensitivity, specificity, positive predicted value, negative predictive value, percentage positive agreement, percentage negative agreement, percentage overall agreement, and overall diagnostic accuracy of QIAstat-Dx SARS-CoV-2 assay (as part of QIAstat-Dx Respiratory Panel)

Completion date
01/04/2021

Eligibility

Key inclusion criteria
1. Is a patient in ED, AMU, HDU, GICU, medical wards, or another location within Southampton General Hospital, University Hospital Southampton NHS Foundation Trust (UHS)
2. Aged ≥18 years old
3. Can be recruited to the study within 24 hours of presentation to hospital
Plus:
4. Has acute respiratory illness (ARI)*
OR
5. Does not have ARI but is a suspected case of COVID-19 according to the current PHE case definition OR
6. Does not have ARI or fulfil the PHE case definition of a suspected case but testing for SARS-CoV-2 is considered necessary by the responsible clinical team
*An episode of acute respiratory illness is defined as an acute upper or lower respiratory illness (including rhinitis, rhino-sinusitis, pharyngitis, pneumonia, bronchitis and influenza-like illness) or an acute exacerbation of a chronic respiratory illness (including exacerbation of COPD, asthma or bronchiectasis). For the study, acute respiratory illness as a provisional, working, differential or confirmed diagnosis must be made by a treating clinician

Staff testing
Non-hospitalised hospital staff members may be included in the post-implementation phase of the study, if they satisfy the other inclusion and exclusion criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1055

Key exclusion criteria
1. Not fulfilling all the inclusion criteria
2. Declines nasal/pharyngeal swabbing
3. Consent declined or consultee consent declined
4. Already recruited to the study in the last 30 days

Date of first enrolment
20/03/2020

Date of final enrolment
29/04/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southampton General Hospital
University Hospital Southampton NHS Foundation Trust
Research and Development (R&D)
Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Southampton NHS Foundation Trust

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Tristan Clark (t.w.clark@soton.ac.uk). Data will be made available in 3 months following publication for a period of 5 years. All of the individual participant data collected during the trial, after de-identification will be made available. It will be available to researchers who provide methodologically sounds proposal to achieve the aims in the approved proposal including individual participant meta-analysis. Proposals should be directed to the above PI. All data will be de-identified. Informed consent will be obtained from all patients. There are no known ethical or legal restrictions currently.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	13/10/2020	Yes	No
Results article	SARS-CoV-2 Viral load at presentation to hospital is independently associated with the risk of death	04/08/2021	09/08/2021	Yes	No
Results article	Combined RT-PCR and Host Response Point-of-Care Testing in Patients Hospitalised with Suspected COVID-19: A Prospective Diagnostic Accuracy Study	09/05/2022	10/05/2022	Yes	No
Results article		21/06/2020	08/04/2024	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Comparison of patients with and without SARS-CoV-2 infection	28/09/2020	08/04/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Protocol (other)		08/04/2020	10/10/2022	No	No
Protocol file	version 2.0	03/06/2020	10/10/2022	No	No