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Clinical study to assess a new rapid COVID-19 test

Submission date
02/02/2024

Recruitment status
No longer recruiting

Registration date
23/02/2024

Overall study status
Completed

Last Edited
22/02/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This clinical study is looking into a new way of testing for the virus that causes COVID-19 using fresh nasal, throat and saliva swab samples. The samples will be collected from NHS staff and their household contacts during usual COVID-19 testing at the hospital. If successful, the new test will be quick (less than 5 minutes) and use an instrument to detect a signal when the virus is found. It is hoped that it will be as reliable as the best tests now in use without still giving a positive reading for those who have recovered and are no longer infectious. The new test works by finding “virions” (whole virus particles) in samples rather than finding leftover bits of virus. These leftover bits are not infectious but can stay in the body for several weeks and continue to show a positive test result by other test methods. The study will collect information about how well the test can find the virus in fresh samples from people with and without the virus. The results of the new test will be compared to the results from the standard NHS polymerase chain reaction (PCR) test done as part of usual staff testing. These results will then be compared to an extra PCR test and to a virus culture test, in which the virus is grown from the swab samples. The study will also compare the sample types (nose with throat swab, nose without throat swab, saliva swab) to see if the site that a sample is taken from affects the result given by the new test. These results will show how well the new test is working and help us improve it.

Who can participate?
People with and without COVID-19 symptoms aged 18 years old and over who have not had symptoms for more than four days

What does the study involve?
All participants will be given a kit with instructions and asked to provide three swab samples, in the same way as with other COVID-19 tests. The participants will do three swabs on one occasion. The first swab will be in both nostrils, the second in one nostril and the back of the throat and the third will swab saliva from around the mouth, tongue and gums. The participant will mix each of the three swabs with liquid in separate tubes, package up the samples and return them to the research team.
The samples will then be sent to the University of Sheffield and analysed using the new test, PCR testing and another test to grow virus from the samples. They may also be further tested using different tests to give us more information about the samples, namely microscopy, mass

spectrometry and ELISA (antibody) tests.
The research team member will make a note of the participant's age, gender, ethnicity, the number of days that they have had symptoms (if any) and the type of symptoms. They will also ask about any COVID-19 tests done including the type of test used (lateral flow or PCR), COVID-19 vaccination status and whether certain medicines are taken.
The hospital will share the NHS PCR test result of each participant with the researchers at the University of Sheffield and the company, Paraytec Ltd.

What are the possible benefits and risks of participating?
Although there are no direct benefits in the short-term for participating, apart from contributing to research, if the test works well in enough people it could help find people infected with COVID-19 and whether they are likely to be infectious more quickly and easily. The hope is also that the technology used in the new test can be applied to other diseases and help future patients with a variety of conditions.

The risks and inconveniences are the same as for doing nasal and throat swabs for any other COVID-19 test. The nasal swabs can be uncomfortable and cause coughing, sneezing or watering eyes but this should not last long. Throat and saliva swabs can cause gagging but again this should stop once the swab is removed. The swabs are widely used, and not expected to cause any permanent issues. Participants will not receive any results from the study testing, and will still receive their NHS PCR test result, so there is no risk of getting a false result from the study.

Where is the study run from?
The study is run by Sheffield Teaching Hospitals NHS Foundation Trust (STH), with the tests being done at the University of Sheffield.

When is the study starting and how long is it expected to run for?
November 2021 to March 2023

Who is funding the study?
Paraytec Ltd is organising the research and the costs of the study are paid for by Paraytec's parent company, Braveheart Investment Group plc.

Who is the main contact?
The main contact for the study is Professor Carl Smythe, c.g.w.smythe@sheffield.ac.uk.

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
309237

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 309237, CPMS 51304, STH 21689, PA-000201-CP

Study information

Scientific Title

A clinical performance study using an optical fluorescence test to detect SARS-CoV-2 virions in participants with and without COVID-19 and compared to participant data from PCR and viral culture

Study objectives
The primary aim of the study is to understand the relationship between the results of the new test and the viral culture and PCR results. This may help find if the new test can show how likely someone is to spread the virus if they test positive for COVID-19.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/05/2022, London Central REC (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8171; londoncentral.rec@hra.nhs.uk), ref: 22/HRA/1004

Study design
Prospective single-centre non-blinded cross-sectional study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Detection of SARS-CoV-2 virions in infected participants

Interventions
This study is a prospective single-centre non-blinded cross-sectional study of anonymised clinical specimens from staff and their household contacts presenting for SARS-CoV-2 clinical testing.

Participants will be recruited from ongoing testing of NHS trust staff and their households at the hospital. A research nurse will find staff and contacts who are suitable as they wait to be tested and then invite them to take part. Once the participant has given informed consent, they will answer questions about their general demography and history of COVID-19 illness, along with details of symptoms and COVID-19 vaccinations.

Participants will provide three swabs on one occasion using a kit provided. The first swab will be in both nostrils, the second in one nostril and the back of the throat (oropharyngeal) and the

third will swab saliva from around the mouth, tongue and gums. The participant will mix each of the three swabs with liquid in separate tubes, package up the samples and return them to the research team. This will end their participation in the study.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
COVID-19 CX300 IVD device

Primary outcome measure
1. Detection of the presence or absence of the SARS-CoV-2 virus in test specimens measured using the CX300 device compared with the results of quantitative polymerase chain reaction (qPCR) as a reference standard on the day of the test specimens being taken
2. The sensitivity and specificity to detect the presence or absence of the SARS-CoV-2 virus measured using the CX300 device and compared with the results of qPCR as a reference standard on the day of the test specimens being taken

Secondary outcome measures
1. Repeatability and reproducibility (intermediate precision) to detect the presence or absence of the SARS-CoV-2 virus measured using the CX300 device compared with the results of quantitative polymerase chain reaction (qPCR) as a reference standard on the day of the test specimens being taken
2. The relationship between signal strength and viral titre measured using the CX300 device compared with the results of qPCR as a reference standard in nasal/oropharyngeal swab samples cultured on the day of the test specimens being taken

Overall study start date
01/11/2021

Completion date
31/03/2023

Eligibility

Key inclusion criteria
Subjects will be 18 years old and over and recruited from NHS staff and their household contacts at Sheffield Teaching Hospitals NHS Foundation Trust.

Subjects that comply with any of the following criteria:
1. Asymptomatic subjects
2. Subjects who have tested positive for COVID-19 via lateral flow testing or PCR testing from a specimen collected and tested within the previous 24 hours
3. Symptomatic subjects with 4 days or less duration of one or more COVID-19-related clinical

symptoms including dry cough, loss of or changes in sense of taste, loss of or changes in sense of smell, fever, stuffy or runny nose, headache, fatigue, sneezing, sore throat, hoarse voice, chills, joint pain, myalgia, night sweats, skin changes, loss of concentration, dizziness, eye soreness, shortness of breath, loss of appetite, diarrhoea, nausea and vomiting.

Participant type(s)
Population

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
125

Key exclusion criteria
1. Without the capacity or English literacy skills to give informed consent
2. Immunocompromised and/or taking oral or injected immunosuppressant medication such as prednisolone, cyclosporin and anticancer drugs or have stopped taking these drugs in the past four weeks
3. Currently taking oral antiviral drugs
4. Tested positive by PCR for COVID-19 in the previous three months excluding tests taken in the previous 24 hours before informed consent for this study

Date of first enrolment
23/09/2022

Date of final enrolment
08/03/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
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Sponsor information

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Paraytec (United Kingdom)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Braveheart Investment Group

Results and Publications

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

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			22/02/2024	No	Yes