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Evaluation of a rapid COVID-19 test (FASTER)

Submission date
10/07/2020

Recruitment status
No longer recruiting

Registration date
21/08/2020

Overall study status
Completed

Last Edited
14/02/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of March 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.

Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.

A fast and reliable diagnostic assay that could be used at the point-of-need (PON) is yet to be developed. We have been working closely with our commercial partners in 2020 on the development of highly sensitive PON tests to facilitate diagnosis at the point of need and to reduce the consequences of diagnostic delay.

This study aims to investigate the relationship between COVID-19 and presence or lower respiratory tract infection (LRTI) with bacteria called Streptococcus pneumoniae (which are commonly found in the throat without necessarily causing symptoms) as well as S. pneumoniae colonisation/LRTI and COVID-19 related disease severity among those that are COVID-19 positive.

Who can participate?
Healthy adults over 18 years old that are attending the hospital with signs and symptoms of coronavirus can participate in the study.

What does the study involve?
The study involves samples being taken at day 0 (consent), day 2, day 7 and day 28. The samples include saliva, throat and nose swabs, nasosorption (blotting paper inserted into the nose to collect some concentrated nasal secretions), urine and blood. Data is collected from hospital case notes, all samples and data collected are annonymous.

What are the possible benefits and risks of participating?
Some sampling including nose swabs and blood samples may cause temporary discomfort or bruising however the sampling is minimally invasive. There are no direct benefits of taking part in the study, participation is helping to develop knowledge and improve diagnostic tests. The nose and throat swab is used to detect the coronavirus and may pick up a positive result where the NHS sample has not been taken or taken at a different time-point that has not detected the virus.

Where is the study run from?
Liverpool School of Tropical Medicine (LSTM)

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

Who is funding the study?
Pfizer (USA)

Who is the main contact?
Angela Hyder-Wright, angela.hyder-wright@lstmed.ac.uk or 2volresearch@lstmed.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)

282147

Protocol serial number
20-036

Study information

Scientific Title
Facilitating A SARS CoV-2 TEst for Rapid triage (FASTER)

Acronym
FASTER

Study objectives
This project will evaluate point-of-need (PON) tests for the detection of the novel strain of coronavirus SARS-CoV-2 causing the rapidly growing deadly outbreak of COVID-19 and will study the association between COVID-19 and S. pneumoniae colonisation and clinical outcome.
We are working with industrial partners who have developed a low-cost, lateral flow assay (LFA) to detect viral circulating antigens and IgM/G against COVID-19 in less than 15 minutes. These PON tests are intended for the rapid triage of patients with fever and/or cough. Furthermore, the PON tests will be formatted as self-tests, offering the additional benefit of deploying widely in the home and community settings. In addition, we will evaluate ELISA assays to detect IgG, IgA and IgM against COVID-19.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/06/2020, National Health Research Ethics Committee South Central Oxford C (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8041; oxfordc.rec@hra.nhs.uk), ref: 20/SC/0169

Primary study design
Observational

Study design
Observational cohort study

Study type(s)
Diagnostic

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

Interventions
Healthy adults over 18 years old that are attending the hospital with signs and symptoms of coronavirus infection can participate in the study. The study involves samples being taken at day 0 (consent), day 2, day 7 and day 28. The samples include saliva, throat and nose swabs,

nasosorption (blotting paper inserted into the nose to collect some concentrated nasal secretions), urine and blood. Data is collected from hospital case notes, all samples and data collected are anonymous.

Intervention Type
Other

Primary outcome(s)
1. Pneumococcal colonisation measured in SARS-CoV-2-positive participants and SARS-CoV-2-negative controls by PCR at baseline, day 2, day 7 and day 28
2. SARS-CoV-2 is detected and quantified by RT-qPCR in NP swabs at baseline, day 2, day 7 and day 28 (for the SARS-CoV-2-positive participants)

Key secondary outcome(s)
1. Levels of inflammation are assessed by levels of 30 cytokines in nasal fluid and serum at baseline, day 2, day 7 and day 28
2. T-cell and B-cell antigen-specific responses are measured by flow cytometry based assays using PBMCS at baseline, day 2, day 7 and day 28
3. Antibody responses against SARS-CoV-2 are measured by ELISA at baseline, day 2, day 7 and day 28
4. Cellular immune responses to SARS-CoV-2 are measured by flow cytometry and functional assays in BAL samples collected at 3 - 6 months and 9 - 12 months (in both SARS-CoV-2-positive participants and SARS-CoV-2-negative controls)

Completion date
14/04/2021

Eligibility

Key inclusion criteria
1. Adults 18 years old
2. Presenting with any of the following COVID-19 symptoms
2.1 Fever ≥37.8°C +/-
2.2. Shortness of breath +/-
2.3. New/ persistent cough
2.4 Clinical or radiological evidence of pneumonia
3. Fluent spoken English - to ensure a comprehensive understanding of the research project and their proposed involvement
4. Capacity to give informed verbal consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Sex
All

Total final enrolment
400

Key exclusion criteria
1. Lack of capacity or unable to perform verbal consent

Date of first enrolment
14/04/2020

Date of final enrolment
14/04/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Liverpool and Broadgreen University Hospital
Prescott Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Aintree University Hospital
Lower Lane
Liverpool
United Kingdom
L9 7AL

Study participating centre
St Helens and Knowsley Teaching Hospitals NHS Trust
Whiston Hospital
Warrington Road
Prescot
United Kingdom
L35 5DR

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Industry

Funder Name
Pfizer

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed 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?
Results article		09/02/2022	10/02/2022	Yes	No

HRA research summary			28/06/2023	No	No
Participant information sheet	version v3.0	31/05/2020	25/08/2020	No	Yes
Participant information sheet	version v3.0	31/05/2020	25/08/2020	No	Yes
Protocol file	version v3.0	06/05/2020	25/08/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes