# Evaluation of a rapid COVID-19 test (FASTER)

Submission date	<b>Recruitment status</b> No longer recruiting
<b>Registration date</b> 21/08/2020	<b>Overall study status</b> Completed
Last Edited 14/02/2022	<b>Condition category</b> 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

## Study website

https://www.lstmed.ac.uk/projects/the-faster-trial-diagnostics-development-for-covid-19

# **Contact information**

**Type(s)** Public

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# Additional identifiers

**EudraCT/CTIS number** Nil known

**IRAS number** 282147

**ClinicalTrials.gov number** Nil known

Secondary identifying numbers 20-036, IRAS 282147

# 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

**Study design** Observational cohort study

**Primary study design** Observational

**Secondary study design** Cohort study

#### **Study setting(s)** Hospital

**Study type(s)** Diagnostic

**Participant information sheet** See additional files

# 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 measure

1. Pneumococcal colonisation measured in SARS-CoV-2-positive participants and SARS-CoV-2negative 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)

# Secondary outcome measures

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)

# Overall study start date

18/03/2020

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

**Age group** Adult

Lower age limit 18 Years

Sex

Both

**Target number of participants** 400

**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** England

United Kingdom

**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

**Sponsor details** Pembroke Place Liverpool England United Kingdom L3 5QA +44 (0)1517053794 lstmgov@lstmed.ac.uk

**Sponsor type** University/education

Website http://www.lstmed.ac.uk/

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

**Funding Body Type** Government organisation

**Funding Body Subtype** For-profit companies (industry)

**Location** United States of America

# **Results and Publications**

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

# Intention to publish date

14/04/2022

## 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?
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
<u>Results article</u>		09/02/2022	10/02/2022	Yes	No
HRA research summary			28/06/2023	No	No