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Evaluating new point-of-care diagnostic tests for COVID-19

Submission date	Recruitment status	[_] Prospectively registered
14/07/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/07/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/06/2024	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The United Kingdom and wider world are in the midst of the 2019 novel coronavirus (SARS-CoV-2) pandemic. Accurate diagnosis of infection, identification of immunity and monitoring the clinical progression of infection are of paramount importance. Widespread population testing has proven difficult in western countries and has been limited by test availability, human resources and long turnaround times (up to 72 hours). This has limited the ability to control the spread of infection and to develop effective clinical pathways to enable early social isolation of infected patients and early treatment for those most at risk.
The life sciences industry has responded to the pandemic by developing multiple new in vitro diagnostic tests (IVDs). To leverage the potential clinical benefit of those tests efficient but robust clinical evaluation is required. Therefore, to optimise resource utilisation in this global pandemic, researchers will conduct a platform adaptive diagnostic study on a national level, utilising a national network of expertise in the evaluation of diagnostic technology. This study will enable the evaluation of multiple tests in three priority areas:
1. Evaluation of the diagnostic accuracy of IVDs for active infection with SARS-CoV-2
2. Evaluation of tests monitoring the immune response to SARS-CoV-2 infection
3. Evaluation of the prognostic value of commercially available tests for predicting prognosis in patients with suspected or confirmed SARS-CoV-2 infection (this arm will not be active immediately but may be activated after initiation).

Who can participate?
Patients aged 18 or over with suspected or confirmed diagnosis of COVID-19

What does the study involve?
Swabs from the participant's nose and throat are taken, along with a saliva and blood sample. Additional samples may also be taken on five occasions over the next 90 days, depending on the test being evaluated at the participating site. This samples would either be tested locally at the participating site, or they may be sent to a central laboratory for testing. Basic data will also be collected from the participant, which includes demographics, presenting symptoms, past medical history, physical examination findings, vital signs and the results of any routine tests

that the participant undergoes as part of their routine care. Follow-up data will also be collected at 30 and 90 days. This will include details of the participant's condition, such as mortality status, requirement for intensive care, organ support and oxygen treatment.

What are the possible benefits and risks of participating?
Whilst there are no individual benefits to being involved in this study, society and the national response to the pandemic will benefit from the confidence that new tests used by the NHS to detect COVID-19 will be accurate, reliable and give the results quickly. Apart from the inconvenience of having further samples taken, there are no additional risks to the participant.

Where is the study run from?
Manchester University NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2020 to October 2022

Who is funding the study?
National Institute for Health Research (NIHR), through the UK Research & Innovation (UKRI) fund (UK)

Who is the main contact?
Unfortunately, this study is not recruiting public volunteers at this time. This is because the research isn’t ready for volunteers yet or the researchers are directly identifying volunteers in certain areas or hospitals. Please do not contact the research team as they will not be able to respond. For more information about COVID-19 research, visit the Be Part of Research homepage.

Study website
Not applicable

Contact information

Type(s)
Public, Scientific

Contact name
Prof Richard Body

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Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
284229

ClinicalTrials.gov number
NCT04408170

Secondary identifying numbers
CPMS 45932, IRAS 284229

Study information

Scientific Title
Facilitating Accelerated CLinical evaluation Of Novel diagnostic tests for COVID-19 (FALCON C-19)

Acronym
FALCON C-19

Study objectives
In response to the COVID-19 pandemic, multiple in vitro diagnostics tests (IVDs) have been rapidly developed to detect SARS-CoV-2 infection or immunity. To meet the urgent demand for increased testing capacity, many IVDs have received emergency use authorization. However, clinical evaluations to date have mainly been single-centre, employing differing reference standards with variable protocols. There remains an urgent need for a multi-site, rapid, and methodologically robust approach to in-context clinical validation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/06/2020, Wales Research Ethics Committee 5 Bangor (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)7970 422139; Wales.REC5@wales.nhs.uk), ref: 20/WA/0169

Study design
Observational; Design type: Validation of investigation /therapeutic procedures

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)

Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Interventions
The following samples will be taken:
1. Combined nasal/throat swab and/or saliva and approximately 15 ml venous blood taken at the time of first contact (baseline/day 0)
2. Combined nasal/throat swab and/or saliva will also be collected on day 1
3. Approximately 2 ml whole blood and/or finger stick blood samples drawn serially on days 1, 3, 5, 9, 30 and 90
Please note, not all of the diagnostic evaluations will require a full sample set. The samples collected will depend on the diagnostic test that is being evaluated at the study site

Data collection
Basic data will be collected from participants about their demographics, presenting symptoms, past medical history, relevant vaccinations, physical examination findings, vital signs and the results of any routine tests that they undergo as part of their clinical care. On follow-up visits, details of the participant's condition will be collected (e.g. mortality status, requirement for intensive care, organ support and oxygen treatment).

Intervention Type
Other

Primary outcome measure
"Standard" diagnostic accuracy of point-of-care tests for active and past COVID-19 infection with reference to the Public Health England reference standard; Timepoint(s): Baseline, Day 1, Day 3, Day 5 Day 9, Day 30 and Day 90

Secondary outcome measures
1. Detection of antibodies to SARS-CoV-2 by a reference method
2. Length of hospital stay measured using clinical notes
3. Development of multi-organ failure measured using clinical notes
4. Critical care admission measured using clinical notes
5. Mechanical ventilation measured using clinical notes
6. Organ support measured using clinical notes
7. Vasopressor use measured using clinical notes
8. SARS-CoV-2 related death measured using clinical notes
Timepoint(s): Day 30 and Day 90

Overall study start date
30/03/2020

Completion date
01/10/2023

Eligibility

Key inclusion criteria
Patients presenting to secondary/tertiary care with possible SARS-CoV-2 infection who require testing, in the opinion of the treating clinician. Those patients may have presented with acute symptoms of COVID-19 (e.g. fever, cough, dyspnoea) or they may be asymptomatic, but require testing for other reasons

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 1000; UK Sample Size: 1000

Key exclusion criteria
1. Impossible or unsafe to obtain the required research samples
2. Prisoners
3. Patients with confirmed previous infection to SARS-CoV-2
4. Patients where sampling is not feasible

Date of first enrolment
01/06/2020

Date of final enrolment
29/04/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester Royal Infirmary
Manchester University NHS Foundation Trust
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Manchester University NHS Foundation Trust

Sponsor details
Research Office, 1st Floor
The Nowgen Centre
29 Grafton Street
Manchester
England
United Kingdom
M13 9WU

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The researchers will endeavour to publish the findings of this research openly, whether their findings are positive or negative. This is likely to be in medical journals, and the findings may also be published on relevant websites. The researchers will endeavour to ensure that all findings are published with open access. They also plan to disseminate the findings to the Department of Health and Social Care.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the fact that much of the data is commercially sensitive. For enquiries please contact the chief investigator Prof. Richard Body (richard.body@mft.nhs.uk).

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No