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A study to evaluate the performance of a novel Lab-on-Chip device for rapid diagnosis of Covid-19 (SARS-CoV-2 infection)

Submission date
26/10/2023

Recruitment status
No longer recruiting

Registration date
30/10/2023

Overall study status
Completed

Last Edited
06/02/2024

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
PCR (polymerase chain reaction) tests are the “gold standard” test used for diagnosing SARS-CoV-2 (COVID-19). It's a test to detect genetic material from a specific organism, such as a virus. The current wait time for a PCR test, which requires that samples are sent to a lab, is anything up to 24 hours.
A team of clinicians, scientists and engineers from the Royal United Hospital in Bath and the University of Bath are developing a diagnostic testing system (called LoCKAmp) designed to give accurate PCR diagnosis of SARS-CoV-2 within 10 minutes of analysis, at clinical standard accuracy but without requiring a lab.
Using miniaturized microchips (microPCR) on a surface the size of a credit card, the test requires only a few droplets (µL-scale samples). The system has been proven functional and accurate in lab tests, is low-cost to produce and incorporates a portable, handheld device, which carries a disposable microchip performing the core biochemical analysis.
The test result is displayed on an accompanying mobile app within 10 minutes of the patient swab insertion.

Who can participate?
Any individual over the age of 18, attending the RUH hospital, who has given their consent to participate in the study, having received a positive SARS-CoV-2 PCR test administered at the hospital.

What does the study involve?
The aim is to carry out a pilot study by recruiting 100 patients over 3 months and asking them to donate an extra swab when they attend the RUH for a routine PCR test. This extra swab will be tested in the LoCKAmp system in a research laboratory, and the results compared to those obtained from the current “gold standard” PCR test. The patient care pathway will not be influenced by the results obtained from the LoCKAmp test.

What are the possible benefits and risks of participating?
Benefits are helping the development of a lower cost and more rapid test for SARS-CoV-2, the

helping the NHS to reduce costs and time spent testing; there are nos risks associated with this test, as the swab material collection is the same as the standard PCR swab test, and the result will only be used to gain research data - it will not affect treatment decisions of the volunteer.

Where is the study run from?
University of Bath (UK)

When is the study starting and how long is it expected to run for?
March 2022 to January 2023

Who is funding the study?
Engineering and Physical Sciences Research Council (UK)

Who is the main contact?
Dr June Mercer-Chalmers, j.d.mercer-chalmers@bath.ac.uk
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Contact information

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Integrated Research Application System (IRAS)
310212

Central Portfolio Management System (CPMS)
52362

Study information

Scientific Title
A study to evaluate the performance of a Lab-on-Chip LAMP device for rapid SARS-CoV-2 diagnosis

Acronym
LoCKamp

Study objectives
To test the correlation of LoCKamp diagnostis results from hospitalized patients with SARS-CoV-2 infection verified by the clinical standard PCR testing and commercial lateral flow tests. Explore any potential limitation/advantage of LoCKamp in identifying asymptomatic patients, patients on ventilation and explore any correlation with other clinical COVID-19 symptoms.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 29/03/2022, West of Scotland REC 3 West of Scotland Research Ethics Service (Ground Floor, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0212; WoSREC3@ggc.scot.nhs.uk), ref: 22/WS/0038

2. Approved 05/05/2022, HRA and Health and Care Research Wales (Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; -; approvals@hra.nhs.uk), ref: 22/WS/0038

Primary study design
Observational

Study design
Observational non-randomized unblinded single-centred 4-month study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Assess the practicalities of undertaking a larger diagnostic accuracy study of the LoCKamp system for detecting SARS-CoV-2

Interventions
Methodology: A pilot study to test the practicalities of undertaking a larger diagnostic accuracy study of the LoCKamp system.
Feasibility issues will include: ability to recruit and patient acceptability; ability to warn of possible false positive/negative testing results; correlation of LoCKamp malfunction with usability and system acceptability; ability to take samples and clinician acceptance.

1. When patients arrive in RUH and test positive for SARS-CoV-2 with the standard PCR test, they will be screened for inclusion/exclusion in the study based on the criteria following and they will be given the option to participate in the study.
2. Should the patients agree to participate, they will be given the attached consent form and accompanying information and have the protocol explained to them. Consent to this study is voluntary; participants will be offered written information and the opportunity to ask any study-related questions before signing written consent.
3. For the consenting patients a nasopharyngeal swab will be collected by the research nurse and placed in 15mL plastic tubes containing 3mL NaCl 0.9% serum, labelled with patient ID and reference number and date, which will blind the academic team from name / address / identification information about the patient.
4. The patients will then proceed to have their standard care, in the clinic.
5. All collected samples stored in fridge at 5C, and collected by a designated study team member on Mondays between 15.00-17.00 on a weekly basis for the duration of the study. On Monday mornings, immediately prior to being collected by the UoB team, half of the collected samples inactivated on site using commercialy available Inactivating Viral Transport Medium and half by thermal treatment in a water bath at 95oC for 1 minute.
6. The inactivated samples then be transported to the University of Bath laboratory for analysis and data collection. (Laboratory staff at UoB blinded to all clinical data).
7. The study team at UoB run the inactivated samples in LoCKamp, lateral flow tests and standard RT-PCR in parallel.
8. No blinding at hospital sites, with treatment decisions made independently, and irrespective of any UoB test results, i.e. no changes to the standard patient care pathway.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
LoCKamp device

Primary outcome(s)
1. Correlation between:
1.1.LoCKamp results for infection condition measured at a single time point.
1.2. Clinical decision of patient infection condition (using standard PCR lateral flow test, administered by health professionals at the RUH hospital site) measured using patient records at a single time point.
2. Data from the clinical record including temperature and any other known COVID-19 symptoms measured at a single time point.

Key secondary outcome(s)

Assess the practicalities of undertaking a larger diagnostic accuracy study of the LoCKamp system by measuring the number of participants recruited during the LoCKamp study period, using patient records/case report forms, at the end of the study

Completion date
31/01/2023

Eligibility

Key inclusion criteria
1. Patients with SARS-CoV-2 positive PCR test
2. Adult >18 years
3. Attendance at hospital
4. Consent gained for study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
11

Key exclusion criteria
1. Consent not gained for study
2. Child < 18 yrs
3. Adult without mental capacity to consent

Date of first enrolment
01/07/2022

Date of final enrolment
30/09/2022

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
University of Bath

ROR
https://ror.org/002h8g185

Funder(s)

Funder type
Research council

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Anonymised electronic storage of the data from the trial is held securely in a DropBox folder held by the University of Bath. The study outcomes have been published in a journal article (https://pubs.rsc.org/en/content/articlelanding/2023/lc/d3lc00441d)
The type of data stored: Anonymised participant data: responses from CRF, laboratory experiments.
The process for requesting access (if non-publicly available): email to the corresponding author: sp2216@bath.ac.uk
Dates of availability: Anytime from the date of publication: 07/09/2023, for the following 5 years.
Whether consent from participants was required and obtained: Informed consent was gained from participants. This data is held at Royal United Hospital, Bath. This data has been archived.
Comments on data anonymization: Researchers had no access to the identifiable data of the participants. Participants were given a study ID to allow for anonymisation. Only research nurses

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/10/2023	06/02/2024	Yes	No
Participant information sheet	version 1.1	11/04/2022	26/10/2023	No	Yes
Protocol file	version 1.1	11/04/2022	27/10/2023	No	No