# 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	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>[X] Protocol</li></ul>
<b>Registration date</b> 30/10/2023	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
<b>Last Edited</b> 06/02/2024	<b>Condition category</b> Infections and Infestations	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 Dr Despina Moschou, D.Moschou@bath.ac.uk

### **Contact information**

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### Additional identifiers

EudraCT/CTIS number Nil known

IRAS number 310212

**ClinicalTrials.gov number** Nil known

Secondary identifying numbers IRAS 310212, 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

#### Study design

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

#### Primary study design

Observational

#### Secondary study design

Case series

#### Study setting(s) Hospital

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**Study type(s)** Diagnostic

#### Participant information sheet

See study outputs table

#### 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

Pharmaceutical study type(s)

Not Applicable

**Phase** Not Applicable

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

LoCKamp device

#### Primary outcome measure

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.

#### Secondary outcome measures

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

#### Overall study start date

29/03/2022

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

Age group

Adult

**Lower age limit** 18 Years

**Upper age limit** 100 Years

Sex Both **Target number of participants** 40

**Total final enrolment** 11

Key exclusion criteria
1. Consent not gained for study
2. Child < 18 yrs</li>
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** England

United Kingdom

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

## Sponsor information

**Organisation** University of Bath

**Sponsor details** Claverton Down Bath England United Kingdom Previously registered a trial +44 1225 388388 nhs-sponsorship@bath.ac.uk **Sponsor type** University/education

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

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, EPSRC

**Funding Body Type** Government organisation

Funding Body Subtype National government

**Location** United Kingdom

## **Results and Publications**

#### Publication and dissemination plan

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

2. Presentation at international conferences

#### Intention to publish date

31/01/2024

#### 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?	
Participant information sheet	version 1.1	11/04/2022	26/10/2023	No	Yes	
<u>Protocol file</u>	version 1.1	11/04/2022	27/10/2023	No	No	
<u>Results article</u>		10/10/2023	06/02/2024	Yes	No	