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Assessment of an artificial intelligence method for determining the result of a COVID-19 lateral flow test

Submission date
14/05/2021

Recruitment status
No longer recruiting

Registration date
16/06/2021

Overall study status
Completed

Last Edited
20/07/2023

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
Rapid lateral flow tests help to find cases of COVID-19 in people who may have no symptoms but are still infectious and can give the virus to others.
The test usually involves taking a sample from your tonsils (or where they would have been) and from your nose, using a swab. You can get a result in 30 minutes.
Lateral flow devices (LFD) can be used to detect COVID-19 infection. Low viral loads as well as human factors can make interpretation of these devices inconsistent between users. We aimed to develop an artificial intelligence reader to interpret lateral flow devices for COVID-19

Who can participate?
Any health care workers invited by NHS Test and Trace can participate

What does the study involve?
Taking a photo of a lateral flow device after testing for COVID-19 as part of the self report process from NHS Test and Trace

What are the possible benefits and risks of participating?
Benefits: To assist improvements in the accuracy of LFD interpretation
Risks: None known

Where is the study run from?
University of Birmingham

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

Who is funding the study?
NHS Test and Trace (Department of Health and Social Care) (UK)

Who is the main contact
Professor Andrew Beggs, a.beggs@bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Andrew Beggs

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Machine learning for determining lateral flow device results for COVID-19 in an asymptomatic population: A diagnostic accuracy study

Study objectives
That use of an AI reader of lateral flow devices is at least as accurate as an expert read from an asymptomatic test site human reader

Ethics approval required
Old ethics approval format

Ethics approval(s)
Public Health England Ethics Committee (exempt as observational with anonymised data only)

Study design
Observational diagnostic accuracy study

Primary study design
Observational

Secondary study design
Diagnostic accuracy study

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Detection of SARS-CoV-2 infection using a lateral flow device

Interventions
1. Participants decide to take a lateral flow test
2. They take the COVID-19 lateral flow test as per the manufacturer's instructions for use
3. They then log onto the NHS Test and Trace website to return their test result
4. They are then invited to take a photo of the lateral flow test they have used, and record their personal details (name, address, date of birth, NHS number) and whether they are reporting the test as negative or positive
5. The result is not returned to the user but is stored for comparison purposes
6. The end user then finishes the process

The whole process takes 35 minutes from end-to-end and there is no follow-up after this.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
AI reader, lateral flow devices

Primary outcome measure

Accuracy of AI reader compared to human readers measured using the test result (i.e COVID lateral flow device) as reported by the user of the test and as determined by the machine learning algorithm at a single time point

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/11/2020

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Any health care worker invited by NHS Test and trace who is willing to participate in the study
2. Aged 18 years or above or adolescents aged 12 - 17 years (self-test and report with adult supervision) or children under 12 years (should be tested and reported by an adult)
3. Without any common COVID-19 symptoms
4. Able (in the Investigators' opinion) and willing to comply with all study requirements

Participant type(s)
Health professional

Age group
Mixed

Sex
Both

Target number of participants
100,000

Total final enrolment
115436

Key exclusion criteria
1. Did not agree with privacy statement
2. Any common COVID-19 symptoms
3. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study

Date of first enrolment
12/03/2021

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Vincent Drive
Birmingham
United Kingdom
B15 2TT

Study participating centre
University of Durham
Stockton Road
Durham
United Kingdom
DH1 3LE

Study participating centre
Sensyne Health
Schrödinger Building, Heatley Road, Oxford Science Park,
Oxford
United Kingdom
OX4 4GE

Study participating centre
NHS Test and Trace
c/o Department of Health and Social Care, Victoria Street
London
United Kingdom
SW1H 0EU

Sponsor information

Organisation
Department of Health and Social Care

Sponsor details
NHS Test and Trace
Victoria Street
London
United Kingdom
SW1H 0EU
+44 (0)207 210 4850
robert.bananathy@nhs.net

Sponsor type
Government

Website
https://www.gov.uk/government/organisations/department-of-health

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Department of Health and Social Care

Alternative Name(s)
Department of Health & Social Care, DH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Preprint then publication in a high impact journal.

Intention to publish date
01/07/2021

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1.0	04/03/2021	08/07/2021	No	No
Preprint results		21/06/2021	12/04/2022	No	No
Results article		18/10/2022	20/07/2023	Yes	No