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Evaluating home antibody test kits for the detection of coronavirus (COVID-19) antibodies

Submission date
18/09/2020

Recruitment status
No longer recruiting

Registration date
21/09/2020

Overall study status
Completed

Last Edited
03/12/2024

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
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.

It is likely, although not certain, that prior infection with SARS-CoV-2 will confer some protection from severe disease on re-exposure. If this occurs the protected individuals will likely have proteins known as antibodies that are specific for SARS-CoV-2 present in their blood. Developing a validated means of identifying individuals with such protection is a pressing public health priority.

One method of assuring wide accessibility of 'immunity' or 'protection' tests for SARS-CoV-2 would be the availability of home testing systems, either in the form of 'bleed at home, test in the lab' formats or as 'completely at home' home testing kits (HTKs) delivered in 'pregnancy test' type format. The EDSAB-HOME study is primarily designed to address the performance and acceptability of the 'pregnancy test' type system.

Fast, high-quality assessment of an HTK for novel coronavirus antibodies is challenging, as multiple HTKs are under development, and timelines for manufacture keep shifting. Also, it is well recognised that test performance may differ markedly in different populations depending on the levels of coronavirus present in the population. For some groups, an HTK that uses a finger-prick blood sample may not be acceptable by may be accepted by healthcare professionals such as are involved in this study. Laboratory based testing for coronavirus antibodies are being deployed for patient screening soon.

In consequence, as this study wishes to determine the performance of a new HTK in target populations a very short timeframe (which is the UK Government requirement), the following are required:
1. A well characterised, volunteer population which is rapidly accessible.

2. A volunteer population which reflects a range of backgrounds and seroprevalences
3. A volunteer population which reflects the UK Government priority groups for testing, which are at present key workers (Police, etc) and Health Care workers.
4. A volunteer population which is large enough to provide enough individual testing positively for the presence of SARS-CoV-2 antibodies and to represent the demographics of the target population.

These considerations have led the study team to design a study featuring a “volunteer bank”. Building this group of volunteers is referred to as “stage 1”. The volunteer bank will be characterised by questionnaires and blood testing. A group of individuals testing positive for the presence SARS-CoV-2 antibodies in stage 1 will be invited to participate in a “stage 2” in which the Home Testing Kits will be evaluated.

Who can participate?
Unfortunately, this study is not recruiting public volunteers at this time. This is because the researchers are directly identifying volunteers in certain areas or hospitals. This study volunteers include healthcare workers and public service workers aged 18 or over, who were working during the UK lockdown in an organisation taking part in the study.

What does the study involve?
Both stages will take place in a workplace clinic. All volunteers who sign up will undertake stage one, and may or may not be invited to take part in stage two.

In stage one of the study participants will be invited to complete the following;
1. An initial online questionnaire which will ask about who participants, their job (to understand the risk of being exposed to, and having previously had, coronavirus), and any recent respiratory and other symptoms which may indicate that they have had COVID-19. It will also ask what participants have been doing (e.g. if they have been self-isolating, working in a healthcare setting, etc.).
2. Visit a “stage one” clinic which will be set up in their workplace, or another convenient location. At this visit, trained staff will take a blood sample of up to 20 ml from a vein (this is a small amount, and is less than 5% of what is usually taken when donating blood). These samples will then be sent off to a laboratory to help develop antibody tests for coronavirus, including home test kits. At the same time, these samples will be tested for the number of coronavirus-fighting T cells, as this may help the researchers to understand antibody results. If the organisation is doing workplace-based screening for COVID-19 antibodies, blood samples will be taken at the same time as your NHS samples, so participants won’t need to give blood twice.A small number of volunteers (about one person in every 10 volunteering), may also be asked to collect a blood sample into a small tube using a finger-prick. This will help to develop the first type of home test kit. After being tested, the samples will be stored for up to 10 years, and will allow future home and laboratory tests to be developed.
3. A short weekly online questionnaire (1-2 min each) for up to six months. This is optional, but a highly valuable, component of this study. These questions will ask whether participants have become unwell in any way in the previous 7 days. This will help to understand the impact of test results on future health. This will only take 1-2 min a week. If participants do not wish to do this, they are able to indicate this when they join the study. he research team will ask to link the information collected in this study to data of whether participants have been admitted to hospital, and whether they have had a COVID-19 test, and its result.

Some participants will be invited back to a clinic at a later date, to try out new home test kits if they become available. Only a subset of the original volunteers will be called back. If participants are invited to come back and do not wish to do so, they are free to decline. Any second visit is

specifically designed to assess the home test kit which can be used and read at home. If participants agree to attend, the process will be similar to the first visit as participants will be asked to:
1. Visit a clinic for blood samples (as your exposure to COVID-19 may have changed between your first and second visit)
2. Complete a short questionnaire about recent health and possible exposure

Participants will be given a finger-prick home testing kit to try in the clinic, with full instructions provided on the day of how to take it. Researchers will watch participants do this in the testing clinic to make sure it can be used successfully and will record their observations. Participants will be asked for feedback on the process and may also be asked to read the results of tests other than their own, to help improve the reading process.

What are the possible benefits and risks of participating?
There are no risks anticipated from taking part in the study. The risks involved in giving blood are minimal. Participants may feel faint when they give blood and/or bruising may appear, however these will both pass and are not harmful. If participants do a finger-prick blood test, the finger may be sore afterwards.

Social distancing will be maintained in the study clinic, anyone with COVID-19 symptoms will be excluded, and the clinic will follow current infection control guidance to minimise the risk of cross-infection between participants, clinic staff and workplace colleagues who may also be contributing. All staff at the clinic will use Personal Protective Equipment, including masks where appropriate.

Participants will be told the results of your antibody tests if they want to know. This may be a benefit for some participants.

Where is the study run from?
Public Health England (UK)

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

Who is funding the study?
Public Health England (UK)

Who is the main contact?
Dr David Wylie
David.wyllie@phe.gov.uk

Contact information

Type(s)
Scientific

Contact name
Dr David Wyllie

Contact details

Public Health England
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University of Cambridge School of Clinical Medicine
Cambridge Biomedical Campus
Cambridge
United Kingdom
CB2 0SR

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
284980

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 45951, IRAS 284980

Study information

Scientific Title
Evaluating detection of SARS-CoV-2 antibodies using home test kits (EDSAB-HOME)

Acronym
EDSAB-HOME

Study objectives
Home antibody test kits for detection of coronavirus (COVID-19) antibodies have sufficient accuracy for individual use

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 02/06/2020, North East - Newcastle & North Tyneside 2 Research Ethics Committee (NHS BT Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ), ref: 20/NE/0166
2. Approved 13/05/2020, PHE Research Ethics and Governance Group (PHE Research Support and Governance Office, Porton Down, Salisbury, Wilts, SP4 0JG), ref: NR0198

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
See attached file ISRCTN56609224_PIS_V04.03_ 30May2020.pdf

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

Interventions
The study design involves the recruitment of a volunteer cohort (Phase I). which will involve three populations:
1. Individuals at higher risk of past coronavirus infection (healthcare workers) and lower risk (e.g. police, fire and rescue service) for COVID-19
2. Individuals at lower risk of past coronavirus infections (e.g. Police, Fire & Rescue Service). We aim to recruit 1000 persons.
3. Individuals within the above groups with proven past coronavirus infection.
This study is recruiting among key worker groups because they are priority groups for antibody testing for coronavirus. Besides the administration of questionnaires and blood tests, there are no interventions. No therapies of any kind are administered.

Recruitment sites will be run in hospitals, police stations, and fire and rescue facilities, for people who are at work in their place of work (not working from home). The main population recruited will be workers in those sites. From the perspective of someone working in such a facility, they will learn of the study via the intranet, mass email, or posters in their place of residence. Persons working in other healthcare facilities who have previously tested positive may also be made aware of the study via DHSC communications, as they are also eligible to be included.

Interested persons can go to a PHE website for more information. A detailed Patient Information Leaflet describes the study, and a web-based questionnaire with a consent form can be completed. There is an opportunity to talk about the study with study investigators, either on-site or (preferably, given infection control considerations) by phone or Skype in advance. If a volunteer wants to proceed, they will be asked to attend a workplace-based study centre to confirm consent and have a blood sample taken.

Thereafter, the volunteer will be asked about their health weekly for up to 6 months via an online question, with text or emails asking them to complete the form.

The volunteer cohort recruited will be characterised using a questionnaire and gold-standard laboratory blood tests. Venous blood samples (up to 20 ml) will be taken by trained phlebotomists, and a sub-set of 5-10% of participants will be asked to provide a capillary blood sample with the support of the trained phlebotomist Recalling people from the volunteer cohort to test new devices will allow the study to carry out tests rapidly on a relatively smaller number

of individuals while comparing the performance of the device when it is in use with the Medicine and Healthcare Regulatory Agency's (MHRA) performance requirements.

A proportion (estimated 500 persons) will be asked back to use home testing kits. The will be asked to give a repeat blood sample. They can decline to attend if they wish. the home antibody test kit will involve a "pregnancy type" fingerprick plus venous blood sample. Participants will be provided with accompanying instructions and information as to what the result means (which will most likely be read by an accompanying app). Researchers will watch participants using the testing kit in the testing clinic to make sure it can be used successfully and will record their observations. Participants will be asked for feedback on the process and may also be asked to read the results of tests other than their own, to help improve the reading process.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Novel home testing kit for SARS-CoV-2

Primary outcome measure
1. Sensitivity, specificity, positive and negative predictive values of home testing kits (HTKs) for previous SARS-CoV-2 infection measured through patient-reported results when using HTKs observed by research staff compared to results from a "gold standard" reference test (laboratory immunoassay) of venous samples between baseline and 1 year

Secondary outcome measures
1. Test accuracy of HTKs when read by a trained professional in detecting anti-SARS-CoV-2 antibody, and in detecting previous SARS-CoV-2 infection. Sensitivity, specificity, PPV and NPV will be calculated based on readings by a trained professional in a clinical setting between baseline and 1 year
2. Agreement between untrained users and trained professionals in the reading of HTKs assessed by the proportion of agreement between the reading of the HTK results by: users of the service; trained professional examining a photograph; and a trained professional in a community setting between baseline and 1 year
3. Feasibility of home photographic recording of HTK and whether this enhances accuracy of recording relative to user reading by comparing the results (binary) from trained professionals "in vivo" to trained professionals when reading the picture between baseline and 1 year
4. Acceptability and usability of the HTKs in the population using semi-quantitative interviews in a clinic type setting between baseline and 1 year
5. Acceptability of the instructions and other advice to be provided to people undertaking the tests and to those who have a positive and a negative result following participant interviews and questionnaires undertaken in a clinic setting between baseline and 1 year

Overall study start date
01/04/2020

Completion date
01/06/2021

Eligibility

Key inclusion criteria
1. Currently working on-site at their place of work
2. Aged ≥18 years
3. Able to read English
4. Has an in-use personal email address and mobile phone

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 3000; UK Sample Size: 3000

Total final enrolment
4842

Key exclusion criteria
1. Is currently experiencing COVID-19 compatible symptoms
2. Has experienced COVID-19 compatible symptoms in the last seven days
3. Meets the definition of “exceptionally vulnerable” on medical grounds, including immunosuppression, previous oncological treatments – these people should not be at work anyway
4. Unable to read normal-sized print with glasses
5. Taking part in vaccine studies

Date of first enrolment
01/06/2020

Date of final enrolment
01/06/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Milton Keynes University Hospital NHS Foundation Trust
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Rotherham NHS Foundation Trust
Rotherham Hospital
Moorgate Rd
Rotherham
United Kingdom
S60 2UD

Study participating centre
Scarborough Hospital
Woodlands Drive
Scarborough
North Yorkshire
United Kingdom
WO12 6QL

Study participating centre
York Teaching Hospitals NHS Foundation Trust
York Hospital
Wiggington Rd
York
United Kingdom
YO31 8HE

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre

Cheltenham General Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
Lancashire Fire & Rescue Service – Training Centre
Southport Road
Euxton
United Kingdom
PR7 6HJ

Study participating centre
Lancashire Police Headquarters
Saunders Lane
Hutton
United Kingdom
PR4 5SB

Sponsor information

Organisation
Public Health England

Sponsor details
Wellington House
133-155 Waterloo Road
London
England
United Kingdom
SE1 8UG
-
Elizabeth.coates@phe.gov.uk

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type

Government

Funder Name
Public Health England

Alternative Name(s)
PHE

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
Planned publications in peer-reviewed journal.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
Non-identifiable datasets generated during and/or analysed during the current study will be available for academic use upon request from PHE's Office for Data Release (ODR) https://www.gov.uk/government/publications/accessing-public-health-england-data/about-the-phe-odr-and-

accessing-data, subject to their proposed use being compatible with the consent obtained from individuals, and an analysis of the risk of identifying individuals.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V04.03	30/05/2020	21/09/2020	No	Yes
Protocol file	version v1.3	14/09/2020	21/09/2020	No	No
Preprint results	Comparing AbC-19™ Rapid Test, OrientGene COVID IgG/IgM Rapid Test Cassette, SureScreen COVID-19 Rapid Test Cassette, and Biomerica COVID-19 IgG/IgM Rapid Test	01/02/2021	13/08/2021	No	No
Results article	AbC-19 Rapid Test	11/11/2020	13/08/2021	Yes	No
Results article		22/09/2022	29/09/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Association between self-reported and antibody detection	26/03/2021	03/12/2024	Yes	No
Other publications	Pilot study within EDSAB-HOME	19/01/2021	03/12/2024	Yes	No
Results article	Accuracy of four lateral flow immunoassays	04/06/2021	03/12/2024	Yes	No