ISRCTN53701620 https://doi.org/10.1186/ISRCTN53701620

COVID-19 home antibody testing study

Submission date
26/07/2023

Recruitment status
No longer recruiting

Registration date
08/08/2023

Overall study status
Completed

Last Edited
05/09/2023

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
The COVID-19 home antibody testing study will invite Avon Longitudinal Study of Parents and Children (ALSPAC) participants who previously completed the COVID-19 questionnaire to complete a home antibody test. This is part of a collaborative effort across UK cohorts to collect serological data on past infection status. In particular, cohorts have been selected to provide information on prevalence across important areas of variation – ethnicity, age, socioeconomic status and geography.

Who can participate?
Volunteers aged 28 to 50 years old of the ALSPAC longitudinal study

What does the study involve?
This is an antibody research study. In this study, the results of antibody tests that participants have taken at home are used to help understand how many people in Children of the 90s may have been infected with the virus which causes COVID-19.

What are the possible benefits and risks of participating?
The aim of the study was to have results that inform public policy/public health in the time of a pandemic. Risks include potential bruising associated with the test kit.

Note, this was an antibody research study rather than a medical device study. Covid19 test kits had not been licensed when this study ran. Because of this, the study was run as a device study.

Where is the study run from?
ALSPAC (Children of the 90s), University of Bristol (UK)

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

Who is funding the study?
1. Medical Research Council (UK)
2. Wellcome Trust (UK)
3. University of Bristol (UK)

Who is the main contact?
Nicolas Timpson, N.J.Timpson@bristol.ac.uk (UK)

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
B3566, CPMS 46980

Study information

Scientific Title
Serological testing for COVID-19 in ALSPAC (G0/G1)

Study objectives
Serological testing for COVID-19 in ALSPAC (G0/G1) (Lay title: COVID-19 home antibody testing study) will invite ALSPAC participants who have previously completed a COVID-19 questionnaire to complete a home antibody test.

This is part of a collaborative effort across UK cohorts to collect serological data on past infection status. In particular, a set of cohorts have been selected to provide information on prevalence across 4 important areas of variation – ethnicity, age, socio-economic status and geography. (Please note each cohort is running its studies separately and are have its own protocol and route to ethics approval).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/07/2020, ALEC - ALSPAC ethics and Law committee (ALSPAC (Children of the 90s), Bristol, BS8 2BN, United Kingdom; +44 (0)117 455 3687; lynn.molloy@bristol.ac.uk), ref: 110264

Study design
Case-control across within a longitudinal study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
COVID-19 home antibody testing study

Interventions
Our outcome measure is lateral flow test derived evidence of positive antibody response to COVID-19 given knowledge of the sensitivity and specificity of the Fortress Home Test kit. This is relevant given our objectives in this work.

The broad objective of this work (and contribution to the work already underway by REACT and UKBiobank) is the collection of epidemiological-grade biological test data for COVID-19 infection across a series of select studies across the UK which provide information on prevalence across 4 main axes of variation important for developing mitigation strategy relevant evidence (age, geography, socio-economic position, ethnicity/ancestry) and with the ability to assess this against information on existing comorbidities. The study's aim is to have results that are policy useful in a short period reflecting the burden of COVID-19 retrospectively across these

important gradients but also to allow for the effective planning of research into the nature of the events before, during and after infection. This can only be done in longitudinal studies with retrospective data that are continuing (and part of funded examinations into COVID-19 studies) in the future. The Avon Longitudinal Study of Parents and Children (ALSPAC) is the first of 5 studies to have DHSC procured Fortress lateral flow tests available to do this.

This approach will use the same testing approach as the existing REACT-2 study (https://www.reactstudy.org) and consequently, methods are based directly on this successful investigation which has recruited and tested over 100,000 participants. Participants are invited to read the instructions of the antibody kit and do the test themselves at home. The test uses a drop of blood taken from your finger. An instruction booklet is provided with the test for detailed guidance on taking the test.

Participants are also asked to go online to complete a short questionnaire that will ask them to:
1. Record any COVID-19 symptoms you may have had in recent months
2. Record your test result
3. Upload a photograph of your test result (this step is optional)
In total, this should all take around 45 minutes.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
COVID-19 home antibody test

Primary outcome(s)
Covid 19 infection status measured using a COVID-19 home antibody test at one timepoint

Key secondary outcome(s))
The are no secondary outcome measures

Completion date
20/01/2021

Eligibility

Key inclusion criteria
Eligible participants in ALSPAC, a longitudinal study

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
28 years

Upper age limit
50 years

Sex
All

Key exclusion criteria
1. Any participant who responded ‘No’ to the question that asked if they would be happy for the study team to send information about research involving testing for COVID-19 in the ‘Learning more about COVID-19’ questionnaire
2. Increased risk of bleeding (participants will be asked at the consenting stage to self-declare any issues related to bleeding disorders)
3. Participants outside the UK. Costs and timescales for postage outside the UK make this impractical.
4. Participants who are flagged as deceased, withdrawn, no to questionnaires and no to contact.

Date of first enrolment
16/09/2020

Date of final enrolment
14/10/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
At participants homes
ALSPAC (Children of the 90s)
Population Health Sciences
Oakfield House
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Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
University of Bristol

Alternative Name(s)
Universitas Bristolliensis, bristoluniversity, bristoluni

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Through numerous media types, the ALSPAC communications team continue to summarise and describe the footprint of ALSPAC research (http://www.bristol.ac.uk/alspac/covid-19/). This includes usual social media routes and looks to acknowledge the diversity of the study. This is an essential addition for a volunteer participant group like ALSPAC as it provides an important route to disseminate results aimed specifically at population-based or epidemiological findings. Please find a link to ALSPAC's Access Policy - ALSPAC_Access_Policy.pdf (bristol.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/01/2023	07/08/2023	Yes	No
Funder report results		24/01/2022	07/08/2023	No	No
Participant information sheet	version 0.1		07/08/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		22/05/2022	07/08/2023	No	No
Protocol file	version 2.1	01/08/2020	07/08/2023	No	No