ISRCTN55886926 https://doi.org/10.1186/ISRCTN55886926

Investigation of COVID-19 symptoms and potential immunity in the general population

Submission date
28/05/2020

Recruitment status
No longer recruiting

Registration date
01/06/2020

Overall study status
Completed

Last Edited
07/07/2020

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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.
In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.
Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.
This study aims to track up to 90,000 individuals across England to provide scientists and national decision-makers with detailed information to help control and understand the COVID-19 pandemic. The study will investigate why some people have COVID-19 symptoms and others don't, and determine the risk factors for infection. It will help to determine the extent of infection in the general population and help to design new ways to prevent and treat such infections.

Who can participate?
Individuals who participated in the INTERVAL, COMPARE or STRIDES BioResource studies

What does the study involve?
Participants will be asked to provide monthly questionnaire information and a subset of willing participants will be asked to provide monthly fingerprick blood samples.

What are the possible benefits and risks of participating?
There are no direct benefits to the study participants. The findings from this study will be

discussed with key government agencies responsible for helping with the COVID-19 pandemic (e. g., Public Health England). There is no risk associated with participation.

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

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

Who is funding the study?
University of Cambridge (UK)

Who is the main contact?
Unfortunately, this study is not recruiting public volunteers at this time. Please do not contact the research team as they will not be able to respond. For more information about COVID-19 research, visit the Be Part of Research homepage.

Study website
https://www.trackcovid.org.uk

Contact information

Type(s)
Scientific

Contact name
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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
283239

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2.0; IRAS 283239

Study information

Scientific Title
TRACK-COVID: a population-based epidemiological investigation of COVID-19 virus infection

Acronym
TRACK-COVID

Study objectives
To understand the frequency and evolution of symptoms compatible with COVID-19 and to define and monitor the evolution of population immunity by assay of biomarkers (e.g., IgG antibodies to SARS-CoV-2).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/05/2020, Nottingham Research Ethics Committee 2 (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8035, +44 (0)207 104 8103; nottingham2.rec@hra.nhs.uk), ref: 20/EM/0121

Study design
Longitudinal observational study

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Community

Study type(s)
Screening

Participant information sheet
https://www.trackcovid.org.uk/files/2020/05/Appendix-14-TRACK-COVID-study-PIS-v1.0-22.04.2020-2.pdf

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) symptoms and seroprevalence in the general population

Interventions
Participants will be asked to provide monthly online questionnaire information for 12 months. The questionnaire will ask about COVID-19 related symptom experiences within last month, current medication as well as questions related to wellbeing. A subset of participants will be asked to provide a monthly blood sample (obtained at home via finger prick) for 12 months.

Intervention Type
Other

Primary outcome measure
1. Symptoms compatible with COVID-19 measured using online questionnaire information monthly for 12 months
2. Population immunity measured using assay of biomarkers (e.g., IgG antibodies to SARS-CoV-2) on blood samples (obtained at home via finger prick) monthly for 12 months

Secondary outcome measures
1. Asymptomatic or subclinical infections in the population measured using self-reported questionnaire data monthly for 12 months
2. Immunological evidence of previous SARS-CoV-2 infection measured using antibody tests monthly for 12 months
3. Risk factors for subsequent development of any, mild and severe COVID-19 like illnesses (correlates of protection) measured using self-reported monthly questionnaires with concurrent assessment of SARS-Cov-2 specific antibody levels monthly for 12 months
4. Duration of protection from COVID-19 like illness after confirmed infection, measured using SARS-Cov-2 specific antibody levels monthly for 12 months

Overall study start date
27/03/2020

Completion date
06/06/2021

Eligibility

Key inclusion criteria
1. Have previously taken part in the INTERVAL, COMPARE or STRIDES studies
2. Have an email address for study participation
3. Reside in mainland England
4. Have a good understanding of the English language, both written and oral (study materials are not tailored to support non-English language speakers)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
90,000

Key exclusion criteria
1. Have received three invitations from the INTERVAL/COMPARE/ STRIDES research study team to take part in other studies in the past year
2. Have withdrawn their consent to take part in the INTERVAL/COMPARE/STRIDES study

Date of first enrolment
17/05/2021

Date of final enrolment
17/05/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of Cambridge
Department of Public Health and Primary Care
Strangeways Research Lab
Worts Causeway
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Sponsor information

Organisation
University of Cambridge

Sponsor details

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Sponsor type
University/education

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

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name
NIHR Blood and Transplant Research Unit in Donor Health and Genomics

Funder Name
Health Data Research UK (HDR UK)

Results and Publications

Publication and dissemination plan
1. The study protocol may be published in due course
2. Planned publications in high-end journals following completion of the trial

Intention to publish date
17/05/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sarah Fahle (donorhealth@medschl.cam.ac.uk). Data will be available to other researchers upon review of individual requests. All data will be anonymised.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No