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Early Pandemic Evaluation and Enhanced Surveillance of the coronavirus COVID-19 (EAVE II)

Submission date
10/08/2020

Recruitment status
No longer recruiting

Registration date
17/11/2020

Overall study status
Completed

Last Edited
26/05/2022

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
Following the emergence of the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in December 2019 and the ensuing COVID-19 pandemic, population-level surveillance and rapid assessment of the effectiveness and safety of existing or new therapeutic or preventive interventions is needed to ensure that interventions are targeted to those at highest risk of serious illness or death from COVID-19. We aim to determine the attack rate of SARS-CoV-2, the uptake, and effectiveness of any new pandemic vaccine (once available) and any protective effect conferred by existing or new antimicrobial drugs and other therapies.

Who can participate?
The setting for this project will be approximately all general practices based throughout Scotland, these practices have about 5,400,000 people registered with them and will be included in the project.

What does the study involve?
Data from the general practices will be linked to data from related healthcare appointments, blood tests, and virus tests to create an anonymised national dataset that will allow estimates of attack rate and vaccine or antiviral effectiveness and safety.

What are the possible benefits and risks of participating?
The will be no risks and no direct benefit to patients, rather this project will help inform policymakers, clinicians and the public on the progress of the epidemic and the relative benefits of any public interventions deployed such as antiviral medicines or vaccines.

Where is the study run from?
The project is being jointly led by Public Health Scotland and the Universities of Edinburgh, Strathclyde, Aberdeen, St Andrews and Glasgow (UK).

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

Who is funding the study?
The project is funded by the Medical Research Council (MR/R008345/1) and supported by the Scottish Government (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
114474

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 114474

Study information

Scientific Title
Early Pandemic Evaluation and Enhanced Surveillance of COVID-19 (EAVE II): an observational study using linked Scottish national data

Acronym
EAVE II

Study objectives
To describe the epidemiology of COVID-19 in Scotland using linked routine sources of primary, secondary, mortality, and virological/serological testing data, and in due course, to help establish the effectiveness and safety of existing or new therapeutic interventions against the coronavirus that are not subjected to formal clinical trials.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/07/2020, South East Scotland Research Ethics Committee 02 (Waverley Gate 2-4, Waterloo Place, Edinburgh, EH1 3EG UK; +44 (0)131 536 900; Joyce.Clearie@nhslothian.scot.nhs.uk), ref: 12\SS\0201

Study design
Prospective observational cohort study

Primary study design
Observational

Study type(s)
Other

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

Interventions
This is an observational study, no intervention will be given to patients. Any vaccine programmes implemented in Scotland will be assessed for effectiveness. The study will assess these vaccine programmes using linked routine sources of primary, secondary, mortality, and virological /serological testing data from approximately 5.4million individuals registered with a primary care practice across Scotland. A national linked dataset of patient-level primary care data, out-of-hours, hospitalisation, mortality and laboratory data will be assembled. Self-controlled study designs will be explored to estimate the risk of therapeutic and prophylactic-related adverse events.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vaccine programmes implemented in Scotland

Primary outcome(s)

1. Laboratory confirmed SARS-CoV-2 measured using virological/serological tests between baseline and 9 months
2. Serum from blood samples taken from biochemistry tests (or rapid antibody tests if available) will be used to determine exposure to SARS-CoV-2 infection by the presence of antibodies between baseline and 9 months
3. SARS-CoV-2 infection-related clinical outcomes including general practice, COVID-19 centres and out-of-hours consultations, hospital admissions including secondary bacterial infections and multidrug-resistant bacteria associated with these infections, emergency admissions, out of hours consultations, and deaths between baseline and 9 months

Key secondary outcome(s))
1. Vaccine uptake proportions measured using primary care practice and hospital data between baseline and 18 months
2. Prevention and reduction of SARS-CoV-2 infection-related general practice consultations, hospital admissions including secondary bacterial infections, emergency admissions, out of hours consultations and deaths due to therapies, vaccines, and antimicrobials between baseline and 18 months
3. Adverse events related to therapies, for example, vaccine, antimicrobial administration, or other therapies measured using participant data between baseline and 18 months

Completion date
30/09/2021

Eligibility

Key inclusion criteria
All (anonymised) patient data will be collected

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/2020

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
The University of Edinburgh
Usher Institute
Old Medical School
Teviot Place
Edinburgh
United Kingdom
EH8 9AG

Sponsor information

Organisation
Academic and Clinical Centre Office for Research and Development (ACCORD) (UK)

Funder(s)

Funder type
Research organisation

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

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to public benefit and privacy approvals that state only aggregate data can be published from this project

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2022	26/05/2022	Yes	No
Protocol article	protocol published at:	21/06/2020		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results	non-peer-reviewed results	19/02/2021	23/03/2021	No	No