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ASTERIX: An observational study to identify sub-groups of COVID-19 patients based on their demographic, clinical and laboratory profile, and to determine if these sub-groups can be used to predict severity of disease and response to therapy

Submission date
09/09/2020

Recruitment status
No longer recruiting

Registration date
22/10/2020

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
The new coronavirus disease, SARS-CoV-2, is a rapidly emerging global health threat. Health care systems have been on the brink of collapse across the world, reflecting the absence of effective treatment for severe coronavirus 19 disease (COVID-19). Early data show marked differences in the extent to which patients are affected by the virus, with 80% showing little or no symptoms, while others have severe disease, with a fatality rate of 1-2%, usually as the result of progressive COVID pneumonia. The disease can affect people very differently and this study wishes to identify sub-groups of patients to allow targeting of treatment for maximum impact and minimum risk, ideally using biological signatures, or 'endotypes'. ASTERIX is an observational study that will collect surplus samples (blood, respiratory secretions and urine) and data on COVID patients admitted to hospital. This study aims to identify and define these sub-groups of patients, and demonstrate the link between endotype and severity of disease and likely response to treatment.

Who can participate?
All patients 8 years and over admitted to hospital with suspected COVID-19 are eligible to participate.

What does the study involve?
There are no specific trial activities. Patients will be asked to give consent verbally to have their clinical data collected, and for any surplus samples of blood, respiratory secretions, and urine collected during admission and up to 1 year afterward to be available for research purposes.

What are the possible benefits and risks of participating?
There is no direct benefit to the patient, however, the data collected may provide information that can improve future care for COVID-19 patients.

Where is the study run from?
The study is co-ordinated by the CRUK Clinical Trials Unit (UK), and is sponsored by NHS Greater Glasgow and Clyde (UK).

When is the study starting and how long is it expected to run for?
The study will run from April 2020 to January 2022 (updated 21/06/2022, previously: April 2021; updated 05/01/2021, previously: January 2021). Data have been collected retrospectively from January 2020, and patients will continue to be recruited until January 2021.

Who is funding the study?
Chief Scientist Office, Scottish Government (UK) and the National Institute for Health Research (UK)

Who is the main contact?
1. Professor Kevin Blyth (CI)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
283989

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 46231, IRAS 283989

Study information

Scientific Title
Adaptive Stratification of COVID-19 to facilitate Endotype-directed Intervention Studies (ASTERIX)

Acronym
ASTERIX

Study objectives
That it is possible to identify discrete sub-groups of patients (endotypes), based on a range of demographic, clinical, and laboratory biomarkers, that predict:
1. Progression though different stages of disease severity
2. The likelihood of response to therapies

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/05/2020, West of Scotland REC 5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 20/WS/0077

Study design
Observational cohort trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Interventions
The study aims to achieve the following:
1. Recruit between 600 and 1200 participants with appropriate approvals
2. To acquire and record the necessary biological and outcome data using direct electronic

medical record (EMR) capture and a bespoke data collection tool embedded in COVID19 clinical care (the NHS GGC COVID19 assessment tool).
3. Provide a structured biobanking infrastructure, with surplus biological samples linked to clinical data, and a resource for observational, translational and interventional studies
4. Develop different statistical models based on the data collected for progression to three adverse outcomes: 4.1. COVID-19 Pneumonia
4.2. Development of respiratory failure, sufficient to prompt escalation to at least Step 6 of the World Health Organisation (WHO) 10-point ordinal scale
4.3. Death from any cause
These models will generate critical information needed to design high impact clinical trials, including the most suitable mechanism(s) of action at different phases of the illness and the event rate at each timepoint based on current standard of care.

Data Collection
Data will be extracted from clinical record into the NHS GG&C Safe Haven. Automated processes will capture most data fields. However, daily clinical data (e.g. oxygen requirement, clinical observations, vital status) will be collected by ward staff, using a bespoke bedside data collection tool embedded in clinical care (the NHSGGC COVID19 assessment tool). This information will constitute the routine clinical record therefore no study visits will be required.

Biological Sample Processing and Banking
No study specific blood samples will be taken. Surplus blood (+/- any surplus respiratory secretions and urine) will be collected from the laboratories at Baseline (Day 0) and where possible in a series of follow-up windows that span the course of admission (up to 14 days). If blood samples are sent from any hospital follow-up visit within 1-year these will also be banked. Immediate blood sample processing will allow storage of plasma, serum and Peripheral Blood Mononuclear Cells (PBMCs) for COVID research.

Statistical Analyses
The target sample size of 600-1200 will yield 400-800 confirmed cases. These numbers will be sufficient for the primary statistical analyses (generation of reliable models for each progression event). The content of these models will include the routinely available clinical data, the result of blood test performed in clinical practice and the results of a limited number of additional tests performed on the surplus blood samples. These additional assays will include measurements implicated in COVID-19 series, but not routinely measured by clinical teams (e.g. Troponin, D-Dimer). Multivariable predictive models (endotypes) will be generated for each progression event using logistic regression, and the performance of any developed models will be validated in an independent data set.

Intervention Type
Other

Primary outcome measure
To acquire and record the necessary biological and outcome data by extracting electronic medical records held by the NHS trust Safe Haven, collected at various timepoints by automated processes. Daily clinical data (e.g. oxygen requirement, clinical observations, vital status) will also be collected by ward staff using a bedside clinical collection tool embedded in clinical care daily clinical data (the NHSGGC COVID19 assessment tool). Biological materials (e.g. blood, respiratory secretions, urine) for potential translational research will be surplus material from that routinely collected during the hospital admission, and also any follow-up hospital visits within 1 year.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/04/2020

Completion date
31/01/2022

Eligibility

Key inclusion criteria
1. Admitted to hospital with suspected COVID-19

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 600; UK Sample Size: 600

Total final enrolment
6000

Key exclusion criteria
1. Aged <8 years (lower age limit aligns with current NHSGGC Biorepository REC approval for storage and use of surplus tissue)

Date of first enrolment
01/01/2020

Date of final enrolment
30/01/2021

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre

NHS Greater Glasgow and Clyde
J B Russell House Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.uk/

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government

Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

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 publication in a high-impact peer reviewed journal estimated December 2021.

Intention to publish date
31/10/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from NHSGGC safe haven (safehaven@ggc.scot.nhs.uk). The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1.0	11/05/2020	05/11/2020	No	No
HRA research summary			28/06/2023	No	No