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CCP Cancer UK Study. Companion study to educate and inform practice and guidelines regarding COVID-19 infection in cancer patients

Submission date
06/10/2020

Recruitment status
No longer recruiting

Registration date
10/11/2020

Overall study status
Completed

Last Edited
13/05/2024

Condition category
Cancer

[X] 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
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. In March 2020, it was 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.

Currently, there is extremely limited information regarding the risks posed by SARS-CoV-2 to patients with cancer. This study aims to understand the presentation, management and outcomes of patients with cancer. The influence of cancer type and treatment will be explored as well, and the existence of a large dataset of COVID patients including both cancer patients and patients without cancer, allows a comparison between these two groups which can be adjusted for other confounding variables such as age and co-morbidity. The overall objective of the CCP-CANCER UK is to provide information that would educate as well as help inform current practice and development of guidelines globally with regard to COVID-19 infection in cancer patients, in both haematological and solid malignancies (ICD-10 C00x to D49x, all morphologies).

Who can participate?
Patients with COVID-19 who have with a diagnosis of a solid or haematological malignancy. The main population will be from patients who have been recruited to the UK Clinical Characterisation Protocol (CCP-UK) study.

What does the study involve?
This is a prospective observational cohort study specifically for cancer patients which will be recruited alongside the Principal ISARIC CCP-UK protocol in the UK. The study is an observatory, data collection study.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to any participants; there are no interactions with the study team and unlikely participants will be aware of their data being used in this study.

Where is the study run from?
The study is managed by the Liverpool Clinical Trials Centre, under the Sponsorship of Clatterbridge Cancer Centre NHS FT (UK)

When is the study starting and how long is it expected to run for?
August 2020 to March 2022

Who is funding the study?
CCP Cancer UK is funded by the UKRI on a rapid call grant for COVID research.

Who is the main contact?
The Study coordinator will be contacted on CCPcanceruk@liverpool.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Study Coordinator

Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
285044

ClinicalTrials.gov number
NCT04603105

Secondary identifying numbers
CPMS 46602, IRAS 285044

Study information

Scientific Title
CCP-Cancer UK: Clinical Characterisation Protocol for Severe Emerging Infections in the UK (CCP-UK) – a prospective companion study for patients with cancer and COVID-19

Acronym
CCP-Cancer UK

Study objectives
The purpose of CCP-CANCER UK study is to obtain additional data from patients with cancer who were/are recruited into the Principal CCP-UK study which is the key national protocol for characterising COVID19 in the UK population. This study is designed to supplement, not replace, the Principal CCP-UK protocol. This study will be open to research sites who are currently participating in the Principal CCP-UK study. The CCP-Cancer UK study will run for two years. An additional specific cancer data set will be collected from participant's existing medical records. This cancer specific information when combined with the rich data set related to the COVID-19 episode (derived from CCP-UK) will enable a full understanding of COVID-19 in patients with cancer as well as enable a comparison with non-cancer patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/08/2020, East Midlands - Leicester Central REC (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 104 8388; leicestercentral.rec@hra.nhs.uk), ref: 20/EM/0205

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
No participant information sheet available

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

Interventions
This is a prospective observational cohort study collecting a cancer specific dataset from participants enrolled onto the CCP-UK study.

The CCP-CANCER UK study is a companion study to the Principal CCP-UK study which involves the collection of additional data from patient case records for patients with proven COVID-19 and a diagnosis of cancer who are enrolled into any tier of the Principal CCP-UK protocol. Linkage of the CCP-Cancer UK data set with the CCP-UK data set will enable outcomes to be determined for COVID-19 patients with a diagnosis of cancer.

Participants on the principal CCP-UK study who fall into the subset of COVID19 patients with a confirmed malignancy will be identified by the CCP-UK research team who will inform the CCP-Cancer UK research team. The CCP-Cancer UK team will contact cancer staff at research sites and request that the CCP-Cancer UK dataset is completed.

Site staff register the participant on the study database. A specific limited CCP-Cancer UK data set will be recorded by the research team at the participating centre from existing medical records. Should this information not be retrievable by the research site a request will be made to cancer registries.

Should the participant have donated samples as part of the principal CCP-UK study access to these will be requested from CCP-UK for analysis.

The CCP-Cancer UK study does not require any additional patient visits, assessments or sample collections as these are all integral to the Principal CCP-UK protocol

Intervention Type
Other

Primary outcome measure
Primary outcome measure as of 30/04/2024:
Measured at the end of the study:
1. Determine the mortality rate in patients with cancer and COVID-19, using data from the CCP-UK study and linked data
2. Identify factors associated with the poor outcomes in patients with cancer and COVID-19, using data from the CCP-UK study and linked data

Previous primary outcome measure:
Measured at the end of the study:
1. Mortality rate in patients with cancer and COVID-19, using data from the CCP-UK study and linked data
2. Factors associated with the poor outcomes in patients with cancer and COVID-19, using data from the CCP-UK study and linked data

Secondary outcome measures
Secondary outcome measure as of 30/04/2024:
Measured using data from the CCP-UK study and linked data throughout the study:
1. Describe the clinical features and severity of COVID-19 in different tumour types
2. Identify other clinical and laboratory variables that correlate with COVID-19 severity and mortality in different tumour types
3. Determine the influence of disease stage, treatment intent and treatment history on the severity and COVID-19 fatality rate
4. Determine the potential influence of genomic variations on the severity and outcome of COVID-19 episodes, where linked genomic data are available for example from ISARIC4C or GenoMICC
5. Describe the use of healthcare resources (including intensive care) in the treatment of COVID-19 in different tumour types.
6. Undertake a matched cohort study using cancer and non-cancer patients with COVID-19, using patients without cancer as controls from the CCP-UK dataset

Exploratory outcome measures:
7. To investigate the biology of SARS-CoV-2 in the context of cancer-associated or iatrogenic immunosuppression
8. To investigate how COVID-19 interacts with cancer-related immunosuppression

Previous secondary outcome measure:
Measured using data from the CCP-UK study and linked data throughout the study:
1. Time to death measured as the time from COVID diagnosis to death by any cause
2. Time to recovery measured as the time from diagnosis to recovery
3. ITU admission
4. Clinical features and degree of severity of infection (Mild – no oxygen requirement, admission length <7 days; Moderate – ward level oxygen administered; Severe – ITU admission, death, NIV, high flow oxygen administered)
5. Clinical and laboratory variables that correlate with COVID-19 severity and fatality rate
6. Healthcare resource use

Exploratory outcome measures:
7. Microbial diversity measured by microbial diversity index (16s rDNA) at baseline and during transition from infection to
convalescence

Overall study start date
11/08/2020

Completion date
31/03/2022

Eligibility

Key inclusion criteria
Patients with proven COVID-19 and a diagnosis of cancer who are enrolled into any tier of the Principal CCP-UK protocol

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 950; UK Sample Size: 950

Total final enrolment
5000

Key exclusion criteria
None in addition to those specified in the Principal CCP-UK protocol:

Exclusion criteria specified in CCP-UK Protocol:
1. Confirmed diagnosis of a pathogen unrelated to the objectives of this study and no indication or likelihood of co-infection with a relevant pathogen
2. Refusal by participant, parent or appropriate representative

Date of first enrolment
21/03/2021

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Liverpool
Department of Molecular and Clinical Cancer Medicine
Sherrington Building
Ashton Street
Liverpool
United Kingdom
L69 3GE

Sponsor information

Organisation
Clatterbridge Cancer Centre NHS Foundation Trust

Sponsor details
Clatterbridge Road
Bebington
Wirral
England
United Kingdom
CH63 4JY
+44 (0)1515565321
maria.maguire2@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.clatterbridgecc.nhs.uk/

ROR
https://ror.org/05gcq4j10

Funder(s)

Funder type
Charity

Funder Name
Clatterbridge Cancer Charity

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

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

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.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The pseudo anonymised data will be stored for CCP Cancer UK on the Liverpool Universtiy REDCAP Server. The anonymised dataset will be transferred to be linked with the ISARIC CCP UK data on the Data Safe Haven at the University of Edinburgh. Data is being obtained under the COPI notice for UPH COVID studies, and a later CAG application for 251 exemption for when the COPI Expires.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 4.0	21/04/2023	13/05/2024	No	No