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A long-term follow-up study of patients with coronavirus (COVID-19) associated pneumonia

Submission date
23/12/2020

Recruitment status
No longer recruiting

Registration date
21/01/2021

Overall study status
Completed

Last Edited
19/03/2021

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
There is limited evidence on the long-term effects of COVID-19 infection. This is due to the recent onset of the pandemic and, therefore, there has not been an opportunity to study patients who have recovered from the infection.

Previous studies suggest that hospitalized patients had residual disease and that this phenomenon may not apply only to critically ill patients. In addition, there have been reports of cardiovascular injury, which may increase the risk of myocardial infarction. Some neurological consequences, such as numbness, paresthesias, and confusion have been reported. The UK National Health Service, in March 2020, predicted that 45% of COVID-19 patients who had been hospitalized will need ongoing medical care, 4% will require inpatient rehabilitation, and 1% may permanently require acute care.

This study will follow patients with COVID-19 associated pneumonia, who have participated in or are participating in Genentech/Roche sponsored studies, for approximately 12 months after hospital discharge or end of the parent study. The study aims to understand the long-term consequences of resolved COVID-19 associated pneumonia.

Who can participate?
Patients with COVID-19 associated pneumonia, who have participated in or are participating in one of the following Genentech/Roche sponsored studies: COVACTA, REMDACTA, MARIPOSA, COVASTIL, or BACC Bay.

What does the study involve?
Patients will provide consent to participate prior to the first assessment of this study (the Baseline visit). This Baseline visit will occur as soon as possible after the patient completes day 60 or discontinues from the parent study. Study visits will occur approximately every 3 months for approximately 12 months, therefore visits will take place at the Baseline visit and 3, 6, 9, and 12 months after. During this study, physical exams, nasopharyngeal swab, CT scans, echocardiograms, lung function testing, blood samples, questionnaires, and walking tests will be used to assess the patients.

Throughout the study, patients will conduct weekly home lung function monitoring using a handheld spirometry device. Data stored in the spirometry device will be uploaded via a smart device (such as a smartphone). Both devices will be provided by the Sponsor.

In addition, patients will be invited to use an optional wearable device (such as a smart watch), provided by the Sponsor, on a continuous basis to capture daily activity and sleep patterns for the duration of the study. Data stored in the wearable device will be uploaded via a smart device. At the end of this study, patients will be required to return the devices.

What are the possible benefits and risks of participating?
There are no additional study drugs or other treatments beyond standard care that will be provided as a result of taking part in this study, therefore no additional risks or benefits are anticipated.

Where is the study run from?
Genentech, Inc (USA)

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

Who is funding the study?
F. Hoffmann-La Roche Ltd (USA)

Who is the main contact?
global-roche-genentech-trials@gene.com

Contact information

Type(s)
Public

Contact name
Mr Clinical Trials

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Additional identifiers

Protocol serial number
ML42746

Study information

Scientific Title

Long-term follow-up study of patients with COVID-19 associated pneumonia who participated in a designated Genentech/Roche sponsored study or Genentech/Roche supported investigator-initiated placebo-controlled or active-controlled study

Acronym
LOPAC

Study objectives
To assess long-term outcomes in adult patients who were hospitalized with COVID-19 associated pneumonia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/09/2020, Advarra IRB (6940 Columbia Gateway Dr #110, Columbia, MD 21046, USA; +1 410-884-2900; no email available), ref: Pro00046520

Study design
Phase IV multicenter observational follow-up study

Primary study design
Observational

Study type(s)
Other

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

Interventions
To assess long-term outcomes in adult patients who were hospitalized with COVID-19 associated pneumonia. Participants will be recruited from Genentech/Roche sponsored studies or any supported Genentech/Roche independent investigator studies for COVID-19 associated pneumonia. Participants will be followed up for pulmonary, cardiac, cognitive, and quality of life outcomes every three months over 12 months. In addition, any encounters with health care professionals/visits at health care facilities outside of the visits scheduled within the study will be recorded.

Intervention Type
Other

Primary outcome(s)
1. Lung texture analysis of high-resolution computed tomography (HRCT) scan of the chest at baseline, 3, 6, 9, and 12 months
2. Lung function measured using pulmonary function tests at baseline, 3, 6, 9, and 12 months
3. Cardiac function measured using echocardiography at baseline, 3, 6, 9, and 12 months
4. Healthcare resource utilization measured using hospitalization, emergency room visits, urgent care/unscheduled visits, physical therapy, and rehabilitation, in addition to other relevant information collected betweenbaseline, 3, 6, 9, and 12 months
5. Patient-reported health-related quality of life, cognitive function, and respiratory symptoms,

measured by the Short Form 36 Question Health Survey Version 2 (SF-36v2), Euro-QoL-5D-5-L (EQ-5D-5L), Living with Idiopathic Pulmonary Fibrosis Symptoms Questionnaire-Modified (L-IPF-M), and Montreal Cognitive Assessment (MoCA) at baseline, 3, 6, 9, and 12 months

Key secondary outcome(s))
1. Peripheral blood biomarkers measured using circulating markers of inflammation, fibrosis, coagulation, or other emerging exploratory markers of disease biology, as appropriate at baseline, 3, 6, 9, and 12 months
2. SARS-CoV-2 infection measured using symptom guided nasopharyngeal swab for COVID-19 real-time polymerase chain reaction (RT-PCR) between baseline, 3, 6, 9, and 12 months
3. Progression or long-term sequelae of COVID-19 disease measured using patient records at baseline, 3, 6, 9, and 12 months
4. Physical fitness measured using the Six-minute walk test (6MWT) and Borg Scale of Perceived Exertion (optional) at baseline, 3, 6, 9, and 12 months
5. Continuous activity and sleep tracking (optional) captured by a wearable device (such as a smart watch) between baseline and 12 months
6. Prevalence and incidence of COVID-19 antibodies measured from blood samples at baseline, 3, 6, 9, and 12 months

Completion date
30/03/2022

Eligibility

Key inclusion criteria
1. Informed consent by any patient capable of giving consent, or, when the patient is not capable of giving consent, by their legal/authorized representative
2. Aged ≥18 years at the time of providing informed consent
3. Able to comply with the study procedures, in the investigator's judgment
4. Participated in any Genentech/Roche sponsored study or any supported Genentech/Roche independent investigator study for COVID-19 associated pneumonia (Note: Includes patients who completed or discontinued early from these studies)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Participation in an interventional study at the time of enrollment or plans to enroll in an interventional study during this study
2. Any serious medical condition or abnormality of clinical laboratory tests that, in the investigator’s judgment, precludes the patient’s safe participation in and completion of the study

Date of first enrolment
29/10/2020

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
United States of America

Study participating centre
Genentech, Inc
1 DNA Way
South San Francisco
United States of America
90404

Sponsor information

Organisation
Genentech, Inc

Funder(s)

Funder type
Industry

Funder Name
Genentech, Inc

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date