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Cohort study for predicting severe disease courses in patients presenting for coronavirus testing to the University of Zurich COVID-19 Testing Center

Submission date
06/04/2020

Recruitment status
Suspended

Registration date
07/04/2020

Overall study status
Completed

Last Edited
26/05/2020

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

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. Those people that get COVID-19 may develop a fever and/or a continuous cough, or develop a more severe disease requiring them to be admitted to a hospital or an intensive care unit.

In 2020, the virus has spread to many countries and has challenged health care systems around the world. Among the people infected with coronavirus, it is very important to identify those that are at a high risk of developing a more severe disease. For example, people that are especially at risk include people aged over 65 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. While some information is already available for patients in the hospital, only little information has been published from outpatient settings.

The main aim of this study is to identify factors that predict hospital admission and poor clinical outcomes in patients presenting for coronavirus testing at the COVID-19 Testing Center at the University of Zurich (Switzerland). This information is important to anticipate severe disease courses in patients presenting for testing in an outpatient setting. Thereby, it will support family doctors and public health professionals to provide the best possible care for patients affected by COVID-19.

Who can participate?
All patients that are tested at the University of Zurich COVID-19 Testing Center will be invited to join the study.

What does the study involve?
Participants will be followed-up through phone calls to gather information about their disease course and health status, as well as on whether they had further health care contacts. The study follow-up will depend on the test result of the participant.

Participants testing positive for COVID-19 will receive three follow-up phone calls after 7, 14 and 60 days. If they had another health care contact, were admitted to a hospital or do not respond to the calls, their family doctors and treating physicians will be contacted for further information.

Participants testing negative for COVID-19 will receive one follow-up phone call after 14 days. If they were tested again for COVID-19 in the meantime, further information will be gathered from their family doctors and treating physicians. Additionally, the swab samples used to test for COVID-19 will be analyzed for other respiratory viruses and bacteria at a later date. This important information will help to differentiate better between COVID-19 and other respiratory diseases.

What are the possible benefits and risks of participating?
This research project is not expected to result in information that is directly relevant to the health of the individual participants. However, the results of this study will be published and shared with practitioners and public health professionals in Switzerland and internationally. Thereby, this study will contribute to improving the diagnosis and management of future COVID-19 patients. The risks of participating in this study are minimal.

Where is the study run from?
The testing will occur at the University of Zurich COVID-19 Testing Center (Switzerland). The study is run from the Epidemiology, Biostatistics and Prevention Institute (EBPI) at the University of Zurich (Switzerland)

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

Who is funding the study?
The study is initiated by the investigators and funded by the Epidemiology, Biostatistics and Prevention Institute at the University of Zurich (Switzerland).

Who is the main contact?
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Study information

Scientific Title
Predicting hospitalization and poor clinical outcomes in patients presenting for SARS-CoV-2 testing in an outpatient testing center in Switzerland - a prospective cohort study

Acronym
UZH COVID-19 Cohort Study

Study objectives
The primary aim of this prospective cohort study is to identify predictors for hospitalization and poor clinical outcomes among patients presenting for SARS-CoV-2 testing in the COVID-19 testing center at the University of Zurich (UZH) in Switzerland, and to leverage real-time analysis of accumulating data to improve the management of patients affected with COVID-19 in this setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/04/2020, the Cantonal Ethics Committee Zurich (Stampfenbachstrasse 121, CH-8090 Zurich, Switzerland; +41 43 259 79 70; Info.KEK@kek.zh.ch), ref: 2020-00711

Primary study design
Observational

Study design
Single-center, prospective cohort study

Study type(s)
Diagnostic

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

Interventions
Patients presenting to the UZH COVID-19 Testing Center for SARS-CoV-2 testing will be enrolled in the cohort study. All patients will undergo routine testing at the testing center. The cohort study-specific follow-up and prospective data collection will depend on the test result.

Patients tested positive for SARS-CoV-2 will receive three calls at 7, 14 and 60 days after their visit to the testing center. Information will be collected about the disease course and current health status, as well as further health care contacts. Further information about the disease course, hospitalization and patient outcomes will be collected from patient records obtained from general practitioners and treating physicians in hospitals.

Patients tested negative for SARS-CoV-2 will receive one call at 14 days after their visit to the testing center. Information will be collected about the disease course and current health status, as well as further health care contacts and retesting. If retested, further information about the second test result will be collected from general practitioners and treating physicians in hospitals. Biological samples obtained for viral testing will additionally be analyzed for further respiratory pathogens.

Intervention Type
Other

Primary outcome(s)
Hospital admission for any reason among patients who tested positive for SARS-CoV-2 within 30 days following initial consultation for SARS-CoV-2 testing. Information will be collected from participants via follow-up phone calls at days 7, 14, and 60 after consultation, as well as via patient records from general practitioners and/or treating physicians in hospitals after 60 days.

Key secondary outcome(s)
For each of the outcome measures, the information will be collected from patients via follow-up phone calls and patient records from their general practitioners and treating physicians in hospitals. Follow-up will take place at 7, 14 and 60 days after initial consultation for patients tested positive for SARS-CoV-2, and at 14 days after initial consultation for patients tested negative for SARS-CoV-2
1. ICU admission among patients who tested positive for SARS-CoV-2 within 30 days following initial consultation for SARS-CoV-2 testing.
2. Use of non-invasive mechanical ventilation for patients who tested positive for SARS-CoV-2 within 30 days following initial consultation for SARS-CoV-2 testing.
3. Use of invasive mechanical ventilation for patients who tested positive for SARS-CoV-2 within 30 days following initial consultation for SARS-CoV-2 testing.
4. Time to hospital admission from initial consultation for SARS-CoV-2 testing for patients who tested positive for SARS-CoV-2.
5. Time to ICU admission from initial consultation for SARS-CoV-2 testing for patients who tested positive for SARS-CoV-2.
6. Change in health status at 2 days, 7 days, 14 days and 60 days from baseline visit or last outcome assessment in patients who tested positive for SARS-CoV-2 at initial testing.
7. Patient-reported health status of patients who tested positive for SARS-CoV-2 at initial testing at 2 days, 7 days, 14 days and 60 days.
8. COVID-19 related in-hospital mortality, 30-day mortality and 60-day mortality of patients who tested positive for SARS-CoV-2 at initial testing.
9. All-cause in-hospital mortality, 30-day mortality and 60-day mortality of patients who tested positive for SARS-CoV-2 at initial testing.
10. Positive re-testing among patients tested negative for SARS-CoV-2 at initial testing.
11. Further health care contact among patients tested negative for SARS-CoV-2 at initial testing.
12. Detection and characterization of further viral and bacterial respiratory pathogens in biological samples among patients tested negative for SARS-CoV-2 at initial testing.

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Present to the UZH COVID-19 Testing Center for SARS-CoV-2 testing following a phone-based triage assessing their eligibility for SARS-CoV-2 testing
2. Provide consent for study participation

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Unable to follow study procedures
2. Insufficient knowledge of the German, English, French, or Italian language
3. Aged <16 years

Date of first enrolment
08/04/2020

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Zurich COVID-19 Testing Center
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Sponsor information

Organisation
University of Zurich

ROR
https://ror.org/02crff812

Funder(s)

Funder type

Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration