

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/04/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/05/2020	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Dr Dominik Menges
dominik.menges@uzh.ch

Contact information

Type(s)

Public

Contact name

Prof Jan Fehr

ORCID ID

<http://orcid.org/0000-0003-1113-9895>

Contact details

Epidemiology, Biostatistics and Prevention Institute (EBPI)
University of Zurich
Hirschengraben 84
Zurich
Switzerland
8001
+41 44 634 46 79
jan.fehr@uzh.ch

Type(s)

Scientific

Contact name

Prof Milo A. Puhan

ORCID ID

<http://orcid.org/0000-0003-4721-1879>

Contact details

Epidemiology, Biostatistics and Prevention Institute (EBPI)
University of Zurich
Hirschengraben 84
Zurich
Switzerland
8001
+41 44 634 46 10
miloalan.puhan@uzh.ch

Type(s)

Scientific

Contact name

Dr Dominik Menges

ORCID ID

<http://orcid.org/0000-0001-5970-1846>

Contact details

Epidemiology, Biostatistics and Prevention Institute (EBPI)
University of Zurich
Hirschengraben 84
Zurich
Switzerland
8001
+41 44 634 46 15
dominik.menges@uzh.ch

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

N/A

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

Study design

Single-center, prospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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.

Secondary outcome measures

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.

Overall study start date

20/03/2020

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

Age group

Adult

Sex

Both

Target number of participants

The target sample is estimated to be about 2000 participants, assuming an estimated 30-day hospital admission rate of 5%. However, real admission rates in the target population are currently unknown and it may be unrealistic that this sample size will be reached. The final analysis will thus rely on the sample size achieved at the time of closure of the UZH COVID-19 Testing Center.

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

Hirschengraben 84

Zurich

Switzerland

8001

Sponsor information

Organisation

University of Zurich

Sponsor details

Epidemiology, Biostatistics and Prevention Institute (EBPI)

Hirschengraben 84

Zurich

Switzerland

8001

+41 44 634 46 15

dominik.menges@uzh.ch

Sponsor type

University/education

Website

<https://www.ebpi.uzh.ch/en.html>

ROR

<https://ror.org/02crff812>

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Results will be published in peer-reviewed scientific journals.

Intention to publish date

31/03/2021

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration