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# AspCOVID-19 study: fungal infection of the airways in severe COVID-19 pneumonia

**Submission date**
06/04/2020

**Recruitment status**
No longer recruiting

**Registration date**
17/11/2020

**Overall study status**
Completed

**Last Edited**
16/04/2021

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## 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. As of March 2020, it is 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.

Bacterial or fungal superinfections are well-known complications of viral infections. Especially, the experiences from critically ill patients with severe influenza pneumonia showed that fungal infection (aspergillosis) is a relevant co-infection.

Based on recent observations it seems that the airway system of patients with COVID-19 pneumonia is exposed in the same way as in severe influenza pneumonia which suggests that infection complications could be similar. Invasive pulmonary aspergillosis may be a relevant co-infection in critically ill patients with severe COVID-19 pneumonia.

Aim of the underlying prospective AspCOVID-19 study is the screening for invasive pulmonary aspergillosis in critically ill patients with severe COVID-19 pneumonia.

Who can participate?
Critically ill patients with severe COVID-19 pneumonia, aged 18 years or above.

What does the study involve?
All mechanically ventilated patients with COVID-19 pneumonia will be screened for invasive pulmonary aspergillosis on day 1, 3, 7, 10, 14 and then every three days after ICU admission and intubation/mechanical ventilation.

What are the possible benefits and risks of participating?
Early recognition of co-infection, especially fungal infections, could be a benefit, because early treatment initiation minimize the risk of complications caused by infections.
As the provided procedures are standard examinations and daily routine in critically ill patients that were also done in critically ill without study participation there is no specific risk for study patients.

Where is the study run from?
Munich University Hospital (Germany)

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

Who is funding the study?
Technical University of Munich (Germany)

Who is the main contact?
Dr Tobias Lahmer, tobiaslahmer@me.com

# Contact information

### Type(s)
Scientific

### Contact name
Dr Tobias Lahmer

### ORCID ID
https://orcid.org/0000-0003-1008-5311

### Contact details
Medizinische Klinik und Poliklinik II
Klinikum rechts der Isar
Technische Universität München
Ismaninger Straße 22I
Munich
Germany
81675
+49 89 4140 9345
Tobias.Lahmer@mri.tum.de

# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Protocol serial number
Nil known

# Study information

### Scientific Title
Invasive pulmonary aspergillosis in severe COVID-19 pneumonia: AspCOVID-19 study

### Acronym
AspCOVID-19 study

### Study objectives
Bacterial and/or fungal superinfection are well-known complications of severe viral infections. Driven from experiences with severe influenza pneumonia we suggest that invasive pulmonary aspergillosis might be a relevant complication of severe COVID-19 pneumonia in critically ill patients.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 22/03/2020, Ethikkommision, Fakultät für Medizin, Technische Universität München (Ismaninger Straße 22, 81675 München, Germany; +49 89 4140-7737; ethikkommission@mri.tum.de), ref 149/20

### Study design
Prospective observational study

### Primary study design
Observational

### Study type(s)
Screening

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

### Interventions
Screening of all mechanical ventilated patients with COVID-19 pneumonia for invasive pulmonary aspergillosis using the galactomannan from serum and broncho-alveolar lavage on day 1, 3, 7, 10, 14 and then every three days after ICU admission and intubation/mechanical ventilation. Combined with standard microbiological testing for bacterials and fungals and standard laboratory parameters (infection parameters: C-reactive protein, procalcitonin , Interleukin 6, leukocyte count, lymphocytes).

### Intervention Type
Other

### Primary outcome(s)
Pulmonary aspergillosis infection measured using the galactomannan from serum and broncho-alveolar lavage on day 1, 3, 7, 10, 14 and then every three days after ICU admission and intubation/mechanical ventilation

### Key secondary outcome(s))
1. Duration of ICU stay measured using patient records
2. Mortality rate measured using patient records
3. Co-Infections measured using patient records
4. Ventilation time measured using patient records
5. Duration of hospital stay measured using patient records

### Completion date
31/07/2020

## Eligibility

### Key inclusion criteria
Critically ill patients with severe COVID-19 pneumonia

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Younger than 18 years old
2. Pregnancy
3. Missed informed consent

### Date of first enrolment
25/03/2020

### Date of final enrolment
30/06/2020

## Locations

### Countries of recruitment
Germany

**Study participating centre**
**Klinikum rechts der Isar**
Medizinische Klinik und Poliklinik II
Technische Universität München
Ismaninger Straße 22
Munich
Germany
81675

# Sponsor information

**Organisation**
Klinikum der Universität München

**ROR**
https://ror.org/02jet3w32

# Funder(s)

**Funder type**
University/education

**Funder Name**
Technische Universität München

**Alternative Name(s)**
Technical University of Munich, TUM

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
Germany

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 17/03/2021 | 16/04/2021 | Yes | No |
| Preprint results | non-peer-reviewed results in preprint | 22/07/2020 | 17/03/2021 | No | No |