Serial measurements in COVID-19-induced acute respiratory disease to unravel heterogeneity of the disease course: design of the Maastricht Intensive Care COVID cohort; MaastrICCht.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23472

Source
NTR

Brief title
MaastrICCht

Health condition

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.

Sponsors and support

Primary sponsor: None. Investigator initiated study.
Source(s) of monetary or material Support: None.

Intervention

Outcome measures

Primary outcome

Clinical data, laboratory results, EIT measurements and vital parameters will be collected within the MaastrICCht cohort. As multiple hypotheses can be investigated within the observational cohort, no predefined primary outcome for the whole cohort will be defined.

Rather, investigators have to submit a data request including a predefined analysis plan according to reporting guidelines appropriate for the type of study (i.e., STROBE for observational studies, STARD for diagnostic studies, TRIPOD for prognostic studies; see the Enhancing the QUAlity and Transparency Of health Research network at www.equator-network.org for detailed information). All external researchers submitting a data request will be required to produce a statistical analysis plan that will be reviewed by the cohort steering committee.

Secondary outcome

x

Study description

Background summary

We will collect clinical variables, vital parameters, laboratory variables, mechanical ventilator settings, chest electrical impedance tomography, electrocardiograms, echocardiography as well as other imaging modalities to assess heterogeneity of the natural course of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in critically ill patients. The MaastrICCht cohort is also designed to foster various other studies and registries and intends to create an open-source database for investigators. Therefore, a major part of the data collection is aligned with an existing national Intensive Care data registry and two international COVID-19 data collection initiatives. Additionally, we create a flexible design, so that additional measures can be added during the ongoing study based on new knowledge obtained from the rapidly growing body of evidence.

Objectives:
1) Investigate the longitudinal relationship between changes in the PF ratio and changes in EIT bio-markers over the course of SARS-CoV-2 induced ARDS .
2) Investigate whether changes in the PF ratio and changes in EIT biomarkers are related to prone position.
3) Investigate whether changes in PF ratio and changes in EIT biomarkers are associated with mortality.
4) Investigate the development of multi-organ failure over time in intensive care patients on mechanical ventilation with SARS-CoV-2 infection; comparing survivors vs deceased.

Study objective

We hypothesize that a comprehensive characterization of the heterogeneity of the natural course of critically ill patients with SARS-CoV-2 will enhance our aetiologic, diagnostic and prognostic understanding of the disease, which ultimately helps to guide Intensive Care resources and patient care.

Multiple hypotheses will be investigated, including but not limited to:
- phenotyping COVID-19 induced respiratory disease using EIT biomarkers during mechanical ventilation could optimize ventilation, timing of prone positioning and possibly affect outcome.
- mechanically ventilated patients, admitted to the Intensive Care Unit (ICU) with SARS-CoV-2 infection who survived the intensive care, have a more favourable development of multi-organ failure over time as compared to patients that died.

Study design

On admission to the ICU, data will be collected regarding demographics, comorbidities, clinical variables, critical illness severity scores (APACHE II, SAPS II) and vital parameters. Daily measurements are recorded regarding vital parameters, laboratory results, ventilator settings and interventions (including medication, dialysis and ECMO) for the duration of ICU stay.
Finally, outcome variables such as mortality, cause of death, mechanical ventilation days, proning, readmission, etc. are collected.

Intervention

None.

Contacts

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Eligibility criteria

Inclusion criteria

- Intensive care admission with signs and symptoms of a viral infection
- Intubated and mechanically ventilated
- PCR positive for SARS-CoV-2 and/or a chest CT scan scored positive based on a CORADS-score of 4-5 by a radiologist

Exclusion criteria

None.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-03-2020
Enrollment:	250
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
No concrete agreements on data sharing have been made yet. Before any data is shared outside the MUMC, a datasharing plan will be drawn up in consultation with the data officer

that conforms to relevant laws and regulations concerning personal data.

Ethics review

Positive opinion
Date: 12-05-2020
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8613
Other	Local institutional review board (METc) of the Maastricht UMC+. : 2020-1565

Study results

Summary results
Tas J, van Gassel R, Heines S, et al. Serial measurements in COVID-19-induced acute respiratory disease to unravel heterogeneity of the disease course: design of the Maastricht Intensive Care COVID cohort; MaastrICCht. medRxiv doi: 10.1101/2020.04.27.20080309