

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

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

|                             |                                                     |
|-----------------------------|-----------------------------------------------------|
| <b>Ethische beoordeling</b> | Positief advies                                     |
| <b>Status</b>               | Werving gestart                                     |
| <b>Type aandoening</b>      | -                                                   |
| <b>Onderzoekstype</b>       | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON23472

### Bron

Nationaal Trial Register

### Verkorte titel

MaastrICht

### Aandoening

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

## Ondersteuning

**Primaire sponsor:** None. Investigator initiated study.

**Overige ondersteuning:** None.

## Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

Clinical data, laboratory results, EIT measurements and vital parameters will be collected within the MaastrICht 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 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.

## Toelichting onderzoek

#### Achtergrond van het onderzoek

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 MaastrICht 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.

#### Doel van het onderzoek

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.

### **Onderzoeksopzet**

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.

### **Onderzoeksproduct en/of interventie**

None.

## **Contactpersonen**

### **Publiek**

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### **Wetenschappelijk**

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None.

## Onderzoeksopzet

### Opzet

|                  |                                                     |
|------------------|-----------------------------------------------------|
| Type:            | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders                                              |
| Toewijzing:      | N.v.t. / één studie arm                             |
| Blinding:        | Open / niet geblindeerd                             |
| Controle:        | N.v.t. / onbekend                                   |

### Deelname

|                         |                      |
|-------------------------|----------------------|
| Nederland               |                      |
| Status:                 | Werving gestart      |
| (Verwachte) startdatum: | 23-03-2020           |
| Aantal proefpersonen:   | 250                  |
| Type:                   | Verwachte startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Ja

## Toelichting

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.

## Ethische beoordeling

Positief advies

Datum: 12-05-2020

Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|----------|----|
|----------|----|

|         |        |
|---------|--------|
| NTR-new | NL8613 |
|---------|--------|

Ander register Local institutional review board (METc) of the Maastricht UMC+. : 2020-1565

## Resultaten

### Samenvatting resultaten

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