Studying coagulation specific for COVID-19 using "Blood-vessel-on-chip" technology.

No registrations found.

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

Summary

ID

NL-OMON27363

Source
Nationaal Trial Register

Brief title
COV-AGULATE

Health condition

COVID-19

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: ZonMw, dossier number: 50-56300-98-194

Intervention

Outcome measures

Primary outcome

Percentage of endothelial surface in the blood-vessel-on-chip model that is covered by platelets and fibirn ("clotting") upon treatment with COVID-19 patient plasma. Coverage in the blood-vessel-on-chip will be measured by fluorescence microscopy.

Secondary outcome

Several measurements in the patient plasma:
- d-dimer level
- thrombin-antithrombin complexes (TAT)
- cytokine levels ((IL-1β, IL-6, and TNF-α)
- Markers of neutrophil extracellular traps (NETs) using ELISA:
a) Myeloperoxidase (MPO)/DNA
b) Citrullinated histone H3
- Tissue factor (TF) expressing extracellular vesicles as measured by a TF-dependent factor Xa activity assay.

Study description

Background summary

Initial reports from China (Zhou et al. , Guan et al.) showed an increase of coagulation activation. These first reports showed:
- Higher d-dimer levels
- Medium prolonged prothrombin time
- Mild thrombocytopenia

During the first COVID wave in the months March and April, several reports showed a high incidence of the development of venous thromboembolism (VTE). For example, Middeldorp et al. showed a cumulative incidence of VTE at 21 days of follow-up was 42% (95% CI 30-54).

This protombotic state contributes in the clinical course of COVID-19 patients. For example, Whichman et al. show that thrombotic complications could lead to a severe clinical outcome in COVID-19 patients.
Despite the evidence that shows the presence of this relation between COVID-19 and coagulation complications, the specific interactions are not yet known.
Therefore we aim to develop an in-vitro model, Blood-vessel-on-chip, that can mimic COVID-19 related hypercoagulability. We also intend to use these models in evaluating new antithrombotic treatments.

Study objective

Blood-vessel-on-chip technology can mimic the hypercoagulability in COVID-19 patients.

Study design

The primary outcome will be measured using fluorescent microscopy.
The secondary outcome will be measured via several laboratory procedures, such as ELISA.

Intervention

Blood taking procedure (total amount of 22.1 mL blood)

Contacts

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Eligibility criteria

Inclusion criteria

- Age of 18 years or older
- A suspected SARS-CoV-2 virus infection
- Need for oxygen supplementation
- CRP level > 50 mg/L
- D-dimer level > 0.5 mg/L
- Ability to provide written informed consent

Exclusion criteria

- History of venous thromboembolism
- Use of anticoagulant therapy at inclusion
- Known hereditary or acquired thrombophilia

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):	17-01-2021
Enrollment:	24
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-01-2021
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	NL9211
Other	METC AMC : METC 2020_256

Study results