Neuroinvasion in COVID-19

No registrations found.

Ethical review	Not applicable
Status	Suspended
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23627

Source
NTR

Health condition

COVID-19

Sponsors and support

Primary sponsor: Zuyderland Medical Centre
Source(s) of monetary or material Support: Neurology dept., possibly ZonMW (application pending)

Intervention

Outcome measures

Primary outcome

SARS-CoV-2 RT-PCR of cerebrospinal fluid

Secondary outcome

- 8-week mortality
- Leukocyte count of the cerebrospinal fluid
- Serum Leukocyte count, C-reactive protein, Lactate dehydrogenase, D-Dimer

Study description

Background summary

Rationale: Acute respiratory failure in COVID-19 may be caused by neuroinvasion of SARS-CoV-2.
Objective: To investigate the prevalence of SARS-CoV-2 presence in the cerebrospinal fluid of patients with a proven SARS-CoV-2 infection and acute respiratory failure.
Study design: Pilot study
Study population: Adult (>18 years of age) COVID-19 patients admitted to the Zuyderland hospital in the Netherlands.
Intervention (if applicable): -
Main study parameters/endpoints: RT-PCR of SARS-CoV2 in the cerebrospinal fluid.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All patients will be exposed to the complications and discomfort associated with diagnostic lumbar puncture, which is considered a low-risk procedure. As patients will be sedated during the procedure, they will not experience periprocedural discomfort. The study is considered group-related as uncovering the pathophysiology of acute respiratory distress in COVID-19 patients may be a starting point for research aimed at improving the prognosis of COVID-19 patients.

Study objective

SARS-CoV-2 is present in the cerebrospinal fluid of COVID-19 patients with acute respiratory failure

Study design

Follow-up after 8 weeks

Contacts

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Eligibility criteria

Inclusion criteria

- At least 18 years of age
- Requires mechanical ventilation
- Proven SARS-CoV-2 infection
- Lumbar puncture possible within 48 hours of ICU admission
- Informed consent provided by either patient or legal representative

Exclusion criteria

- Contraindication for lumbar puncture
- Proven or suspected cerebrospinal fluid leak or other blood-brain barrier defects
- Any condition known to alter cerebrospinal fluid biochemistry
- Known or suspected cause for respiratory failure, other than COVID-19
- Any disease known for decreasing pulmonary capacity or compliance

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:	Suspended
Start date (anticipated):	26-04-2020
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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	NL8526
Other	METC Z : Z2020090

Study results