Serum Amyloid A as a prognostic marker for disease severity and mortality in COVID-19

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON51218

Source
ToetsingOnline

Brief title
SAVID

Condition

- Viral infectious disorders

Synonym
corona, COVID-19, SAR-COV-2

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland
Source(s) of monetary or material Support: Siemens Healthcare Diagnostics Products Gmbh en Stichting Sint Franciscus Vlietland Groep,Siemens Healthcare Gmbh

Intervention

Keyword: biomarker, COVID-19, prognostic, serum amyloid A

Outcome measures

Primary outcome

Part 1 (first 150 subjects):

Difference in sensitivity of blood plasma SAA, CRP, ferritin and PCT levels on day 1, day 3, day 5 and day 7 of hospital stay in patients with severe versus non-severe COVID-19 disease course. The sensitivity of SAA will be compared to that of each parameter (CRP, ferritin, PCT) separately.

Part 2 (after interim analysis and sample size calculation):

Difference in sensitivity of blood plasma SAA and the parameter with the highest prognostic ability (determined in part 1 of the study) on the day with the highest prognostic ability (determined in part 1 of the study) of hospital stay in patients with severe versus non-severe COVID-19 disease course. The main study endpoint of part 2 depends on the outcome of the interim analyses.

Secondary outcome

Sensitivity, specificity, positive and negative predictive values, positive and negative likelihood ratios SAA versus CRP, ferritin and PCT.

Study description

Background summary

Despite advances in knowledge of SARS-CoV-2 infection and coronavirus disease 2019 (COVID-19) treatment, mortality numbers are still significant, and the

course of the disease can be clinically markedly heterogeneous. As such, there is a strong need for prognostic biomarkers early in the disease.

Study objective

The goal of this study is to investigate recent claims from Chinese studies that serum amyloid A (SAA) is a superior prognostic inflammatory marker in COVID-19 when compared to CRP, ferritin and PCT on day 1, day 3, day 5 and day 7 of hospital admission.

Research questions:
1. Estimate the prognostic ability of SAA, CRP, ferritin and PCT as single markers on day 1, day 3, day 5, day 7 to predict a severe course of COVID-19.
2. Estimate the prognostic ability of SAA, CRP, ferritin and PCT as joint markers on day 1, day 3, day 5, day 7 to predict a severe course of COVID-19.
3. Estimate the prognostic ability of SAA, CRP, ferritin and PCT and patient and clinical characteristics as joint markers on day 1, day 3, day 5, day 7 to predict a severe course of COVID-19.
4. Determine the day(s) at which prognostic ability is maximal.

Study design

This is a monocentre, prospective cohort study.

Study burden and risks

Subjects will have a maximum of 3 additional venepunctures during the study. If a central catheter is present blood will be collected from the catheter and no venepuncture is needed. At each time point 1 tube of 10ml of blood will be collected. We estimate the risk and the burden of the subjects as minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

18 years of age or older;
admitted to the COVID-19 cohort ward of the Franciscus Gasthuis & Vlietland hospital for (suspicion of) SARS-CoV-2 infection;
written informed consent.

Exclusion criteria

undergoing experimental interventions for COVID-19;

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-05-2021
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO Date:	08-03-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-07-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-09-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL76080.100.20
Other	NL9082

Study results

Date completed: 31-12-2021

Actual enrolment: 150

Summary results
Trial ended prematurely