The use of the CoLab score in the diagnostic screening to rule out Covid-19

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The aim of the present study is to investigate if the high negative predictive value of the Colab-score hold on when investigating this score in the following cohort of persons:- Care- and cure-personnel of Zuyderland MC who were requesting a SARS-...

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

Summary

ID

NL-OMON51054

Source
ToetsingOnline

Brief title
CORONATE study

Condition

- Viral infectious disorders

Synonym
Corona, Covid-19

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: ziekenhuis zelf (voor rekening van de laboratoria)

Intervention

Keyword: Covid-19, diagnostics, Exclusion, SARS-CoV-2 RT PCR

Outcome measures

Primary outcome

Care- and Cure personnel

Pre-surgery screening

PID nr X

Complaints: Yes/No X

Contact with Covid-19+ person X

Type Surgery X

Intubation surgery: Yes/No X

Date surgery X

Gender.

X X

Age.

X X

Date Covid-19 screening

X X

Time Covid-19 screening

X X

SARS-CoV-2 RT-PCR result

X X

- When positive Ct-value

X X

Date and time final result PCR

X X

CoLab-score f-score

X X

CoLab-score class

X X

CoLab-score final result

X X

Date en time final CoLab result.

X X

CRP

X X

Albumin

X X

LDH

X X

Alk. Phosphase (AP)

X X

GGT

X X

Bilirubin, total.

X X

Leukocytes

X X

Erytrocyten

X X

Eosinophilic granulocytes

X X

Basophilic granulocytes

X X

Secondary outcome

N.a.

Study description

Background summary

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) disease 2019 [COVID-19]) is a global pandemic with millions of cases and hundreds of thousands of deaths. (ref. WHO. Novel coronavirus (2019-nCoV) situation reportsl 2020; CDC U. Coronavirus disease 2019 (COVID-19) cases in US; 2020))
The initial clinical symptoms for COVID-19 are nonspecific and similar to other seasonal viral diseases, which encompasses fever, dyspnoe, dry cough and fatigue. Reverse transcription Polymerase Chain Reaction (RT-PCR) based methodologies have been the gold standard in confirming that the individual presenting with COVID-19 has active viral shedding of SARS-CoV-2 (ref).
However, there are some important limitations to RT-PCR. First, current techniques take up to 6-8 hr in order to obtain first results. Next to this, often laboratories cannot handle the overload. A second important limitation is that RT-PCR, on a nasopharyngeal swab, may result false negatively in the initial phase of the disease, in spite of the presence of typical symptoms (ref Li et al, NEJM 2020; 382(13):1199-1207; Guo et al, Clin Infect Dis 2020; 71(15):778-785; Lippi et al, Clin Chem Lab Med 2020; 58(7): 1070-1076). In addition, the standard test used has an 80% accuracy (compared to chest CT scan results) (Lippi et al,Clin Chem Lab Med 2020), which may depend on the specific level of viral shedding by any individual at the time of sample test. Third, the RT-PCR technique carries a certain cost, which could mean a considerable financial burden weighing upon both health systems and patients (ref. Langer et al, Sc J Traum, Res Emer Med 2020; 28(113)).
A direct consequence of these limitations is the time spent by a large number of patients awaiting results in the emergency department (ED) before a decision

can be taken as to where admit them to, e.g. in isolation wards and intensive care units focused on COVID-19 patients, or in *clean, non-infective* wards of the hospital (ref Langer et al, Sc J Traum, Res Emer Med 2020; 28(113); Grasselli et al, Lancet Resp Med 2020; 27; Chen et al, Lancet 2020; 395(10223): 507-513)).
To mitigate the burden on the healthcare system, while also providing the best possible care for patients, efficient diagnosis and information on the prognosis of the disease is needed. In addition, to prevent reuse of crude limits when ED and hospital resources are exhausted during a coming wave, a predictive model using multivariable analysis could be of great value.
Very recently, an algorithm was developed by de Boer et al, leading to the so-called *Colab*-score. It turned out that this score had a very high negative predictive value (99.15%). This algorithm was validated using our patient dataset gathered during the first COVID-19 wave. The score is calculated using the age of the patient next to the numeric values of 10 routine-laboratory parameters that are regularly requested on the ED (CRP, albumin, total bilirubin, gamma-glutamyltranspherase (GGT), alkaline phosphatase (AP), lactate dehydrogenase (LDH), leukocytes, erythrocytes, absolute numbers of eosinophilic as well as basophilic granulocytes).
This algorithm was built and validated using a dataset in which only patients of the first COVID-19 wave were included (period February till June 2020). It is known that the first wave occurred after the peak of other respiratory infectious diseases (influenza etc). At the moment, we are facing the second wave, which takes place in another period of the year. Fall and winter in the Northern Hemisphere means inclement weather in many areas, with more people spending time indoors. Several holidays take place around the end of the calendar year, and people who celebrate them want to gather, travel, and visit friends and family. From other respiratory infection diseases, it is known that they increase in this period of the year. An explanation is that during colder months, people gather indoors, and it is known that this is a risk for further transmission of the virus.
Another difference in the second COVID-19 wave as opposed to the first one, is the human behavior prompted by state and local government, and a better compliance to these rules, such as physical distancing, handwashing and mask-wearing,

Study objective

The aim of the present study is to investigate if the high negative predictive value of the Colab-score hold on when investigating this score in the following cohort of persons:
- Care- and cure-personnel of Zuyderland MC who were requesting a SARS-CoV-2 RT-PCR screening because of Covid-19 related complaints, or because they were in the neigbourhood of a SARS-CoV-2 infected person
- Patients that needed to be tested for Covid-19 in a pre-surgery screening setting.

As secondary outcome we want to investigate if this CoLab score leads to faster diagnostics. Also we want to investigate if this simple blood test also leads to a responsible decrease in requested RT-PCR's

Study design

It concerns a prospective cohort study, in which we want to include in several weeks enough persons to answer above mentioned questions:
- Cohort 1: Care and cure personnel of Zuyderland MC requesting a Covid-19 RT-PCR test because they have Covid-19 related complaints, or who were in the near neighborhood of a Covid-19 positive person.
- Cohort 2: patients that has to be tested to exclude Covid-19 before they can undergo surgery (pre-surgery screening)

Persons of these cohort will undergo a venipuncture when they have an appointment for a nasopharyngeal swab (SARS-CoV-2 RT PCR assay). An heparin- and an EDTA-anticoagulated blood container (max. 3 ml each tube) will be drawn. In the heparin-blood the following clinical chemical tests will be performed: CRP, albumin, LDH, GGT, AF, total Bilirubin. The EDTA-blood sample will be used for determination of leukocytes, erythrocytes, absolute numbers of eosinophils and basophils. The 10 numeric values of the before mentioned tests will be put into the CoLab-algorithm, together with the age of the person.

The final result of the CoLab-score will be compared with the result of the SARS-CoV-2 RT-PCR assay,

Study burden and risks

Natue and extent of the burden are minimal and risks are negligible, because the load for the person is minimal (only 1 venipuncture).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- care- and cure personnel with Covid-19 related complaints, and who are requesting a screening for Covid-19
- care and cure personnel which had contact with a Covid-19 proven person, and who are requesting a screening for Covid-19
- Patients who will be screened for Covid-19 in a pre-operative screening setting

Exclusion criteria

- Persons <18 years
- Persons known with a proven Covid-19 (< 1 month diagnosed) and are requesting a screening to investigate if they are no longer Covid-19 PCR positive anymore
- Persons that have already more than 10 days Covid-19 related complaints
- Persons that were already vaccinated for Covid-19
- Persons with a deep anaemia (Hb < 5.5 mmol/L)

Study design

Design

Study type: Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2021
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	15-01-2021
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL76483.096.21