The applicability of fieldable and rapid serological and molecular testing for Corona SARS-2 in a Dutch population during the COVID-19 outbreak- a pilot study

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Examining the applicability of a fieldable serological point of care serological test Biozek and Point of care molecular Fluorescent in Situ Hybridization (FISH) technology by Biotrack for the usage of decision making, containment and management of...

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

Summary

ID

NL-OMON49054

Source
ToetsingOnline

Brief title
Research on performance fieldable point of care diagnostics Corona SARS-2

Condition

- Viral infectious disorders

Synonym
Corona Sars CoV-2, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Ministerie van Defensie,
Source(s) of monetary or material Support: MINDEF

Intervention

Keyword: COVID-19, FISH, Molecular diagnostics, Point of care test, Rapid test, Serology

Outcome measures

Primary outcome

Obtaining knowledge on the performance of fieldable point of care testen: will

they provide reliable information on viral replication intermediars of

virusparticles and antigens.

Decision making on which type of body fluid will generate the best results

Secondary outcome

IIs the test applicable under field circumstances lacking well equiped

laboratory facilities.

Study description

Background summary

Reasoning behind the study

Since January 2020 the SARS-CoV-2 viral pandemic results in many cases of COVID-19 worldwide, with an overall case fatality rate of about 2 %. Even though most of the cases (80%) show mild to moderate clinical signs, about 15 % of cases deteriorate into severe illness requiring in 5 % of the cases hospitalization in the intensive care. The (mortality)percentages do differ between countries and local situations. The probability of a bad outcome is age related; the older the more case fatalities are reported. Also presence of comorbities have a significant impact on the severity of the disease.

The Dutch working conditions Act require efforts of the employer to reduce health and safety hazards and impose risk mitigations strategies in order to

create working circumstances that are safe and will not harm (the health of) an employee. This also includes protective measures related to infection with pathogens. The government also has a responsibility towards her employees to imply strategies that are contributing to the longevity and maintenance of physical and mental health of her personnel. Personnel, that is required to fulfill and sustain their tasks required regardless of circumstances and the COVID-19 related difficulties. Military personnel is asked to perform anywhere and anyhow under circumstances where laboratory facilities are minimal or absent.

At this moment a few serological well performing point of care tests are available for usage under field circumstances. A lot of research is ongoing but not for this specific indication. Also, for molecular detection of the infection a limited number of point of care tests are available but not suitable for field conditions that require robustness and resistance against trembling, shaking or under circumstances with limited laboratory facilities. Therefore the health department of MOD NL has been looking for robust, simple and user friendly fieldable equipment and methods to identify COVID-19 cases.The MOD will perform the study in cooperation with the civilian (research) partners. Results will become accessible for both the military as civilian community.

The working hypothesis is that both the Biozek and Biotrack COVID-19 -point of care rapid test, will generate sufficiently reliable data that the results can contribute to development an fine tuning of risk mitigating measures and management.

Study objective

Examining the applicability of a fieldable serological point of care serological test Biozek and Point of care molecular Fluorescent in Situ Hybridization (FISH) technology by Biotrack for the usage of decision making, containment and management of th SARS-CoV-2 infection in a (military) population.

Study design

Prospective, observational, descriptive pilot study.

Study burden and risks

The participant has a contact moment with the main medical researcher to discuss inclusion in the study.
Thereafter two contact moment follow with the sample team lasting about 2 time 20 minutes. It is expected that the collection of blood samples, nasopharyngeal swabs, and saliva collection will induce slight discomfort and that saliva

collection will not.

The participant fills in (using a data safety protected app) a questionnaire at 3 time point, taking about 5 minutes per session. During the first, above mentioned contact moment , the sampling team member will guide the participant through the questions to make sure the next 2 sessions will be completed correctly if they are filling it in on their own.

The risk involved might be hematoma development after/ during blood sampling of slight erosion of the mucus membranes during swab sampling. The measures taken to guarantee respecting the AVG Act should reduce the risk on data leakage to zero or minimal risk.

For military personnel it is of utmost importance to have access to a useful, and reliable fieldable point of care test. The need for this it urgent since it can reduce their uncertainty or feeling of unsafety as long as they have no information on their or their colleagues status if clinical signs develop in their community during operations or missions.
Also commanders have a strong desire to assign in a responsible way their personnel.
Military doctors want to have the possibility to obtain information from their patients about the possibility that COVID-19 the cause of disease, also if laboratory facilities are limited. Since some COVID-19 can rapidly deteriorate, a risk assessment has to be made of disease occurs in remote locations.

If this research is not performed, the capability gaps are not filled and only nonspecific clinical signs have to lead to decision of likelihood of a diagnosis of COVID -19.

In conclusion, the risk for the participant is low in relation to the major impact which validates its operformance*

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

Group 1
• Complete set samples available as complete set from persons being samples before the outbreak of COVID -19 (< jan 2019).
• Other respiratory viral infections well represented, including the common corona viridae

Group 2
• Complete set samples of SARS-CoV-2 PCR RIVM positive person
• COVID-19 related clinical signs
• Inclusion of patients with minor to severe signs
• Date first clinical signs known
• Date first sampling in relation first day of illness known

Group 3-5

Military personnel volunteering to participate
Study approval by 1-MGA/013 procedure, staffing DGO for related AVG notification and cooperation contract with * Sensorium* (see also attachment K6.2 for details)

Group 3: Complete set samples of potentially contaminated military personnel, with no clinical signs

• Participant has had contact with colleague or family member, roommate that has PCR proven COVID19

• Contact was during complaint of this proven patient or in the three days before the start of the signs
• Direct contact is defined by : minimally one working day repeated contact within the 1,5 meter zone
• Date of sampling resulting in positive PCR of the ill contact known
• Date clinical signs of the ill contact known

Group 4: Complete set samples of potentially contaminated military personnel, with clinical signs
• COVID -19 risk contact known
• Clinical signs participant related to COVID-19
• Date start clinical signs risk contact known (thus moment of start clinical signs within incubation period)

Group 5 complete set samples of military personnel in vital functions:
• Military personnel participating in a critical process and in whom potential COVID-19 signs will severely impact the capability and performance of the military unit or assignment.

Exclusion criteria

none

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	26-06-2020

Enrollment:	369
Type:	Actual

Medical products/devices used

Generic name:	Diagnostic serological and microbiological Point of care tests
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-06-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-10-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL74138.041.20

Study results

Date completed: 08-09-2021

Summary results
Trial ended prematurely