Validation and implementation of rapid testing for SARS-CoV-2 in the primary care setting

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Validation of rapid tests for SARS-CoV-2 in primary care emergency services

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

Summary

ID

NL-OMON49821

Source
ToetsingOnline

Brief title
COVID-19 rapid test in urgent primary care

Condition

- Viral infectious disorders

Synonym
Coronavirus Disease 19

Research involving
Human

Sponsors and support

Primary sponsor: HADOKS
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COVID-19, rapid testing, triage, validation study

Outcome measures

Primary outcome

Sensitivity, specificity, positive and negative predictive values of the Abbott

PanBio antigen test in relation to the RT-PCR (reference test).

Secondary outcome

Not applicable

Study description

Background summary

To prevent exposure to SARS-CoV-2 in the healthcare setting, patients are routinely categorized in *suspected COVID-19* and *not suspected COVID-19*. This categorization follows a COVID-19-triage protocol. Patients who request a consultation in primary care, are asked whether they experience symptoms that are suspicious for an (underlying) SARS-CoV-2 infection. However, because these symptoms are shared with common illnesses, many patients are expected to be falsely classified as *suspected for COVID-19*. Examples include a suspicion of appendicitis, or a fever complicating a urinary tract infection. With an improved triaging process, these patients should be accurately categorized as *not suspected COVID-19*, which can reduce the pressure on COVID-19-related healthcare. Additionally, the risk for the patient of being exposed to SARS-CoV-2 when referred to a *corona centre* should not be ignored * especially in the midst of a second wave of infections. Rapid antigen tests hold great potential of improving the triaging process. However, while these rapid tests are in the process of being validated in hospital care, the validity for population of patients in the primary care setting * the majority of patients * is still unknown.

Study objective

Validation of rapid tests for SARS-CoV-2 in primary care emergency services

Study design

A diagnostic intervention study

Study burden and risks

A minor burden for participation in this study, is for the patient to have a second nasopharyngeal-throat swab taken. There are however no risks associated with the swab; at most a nosebleed can occur.

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

All patients 18 years and older who visit the corona urgent primary care facility of the HADOKS (location Haga, Leyweg, The Hague) or the SHR/DDDB

(location Alrijne, Leiderdorp).

Exclusion criteria

Children younger than 18 years of age.
Insufficient understanding of the Dutch language.
Recent (< 12 hours) intake of alcohol.
Administration of remdesivir and/or dexamethasone before study procedures.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2020
Enrollment:	1500
Type:	Anticipated

Medical products/devices used

Generic name:	Abbott Panbio COVID-19 antigen rapid test
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	26-11-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	30-11-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL75741.058.20