ISRCTN13990999 https://doi.org/10.1186/ISRCTN13990999

A diagnostic study comparing different tests for the diagnosis of COVID-19

Submission date
23/06/2020

Recruitment status
No longer recruiting

Registration date
24/06/2020

Overall study status
Completed

Last Edited
17/03/2021

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

Italy has been one of the most affected countries in Europe. The virus has posed an extremely difficult challenge for health units and health workers. Reliable and fast tests for diagnosis at the Emergency room level are of the highest importance. The aim of this study is to assess the performance of different tests for the diagnosis of COVID-19

Who can participate?
Adult patients with symptoms of COVID-19 who provide consent to participate in the study and to the donation of biological samples.

What does the study involve?
All patients presenting to the Emergency Room (ER) of the participating hospital with suspected COVID-19 will be given information about the study and asked for consent to participate. Participants who agree to participate will undergo several diagnostic tests for COVID-19 which involve blood withdrawal and a nose and throat swab.

What are the possible benefits and risks of participating?
Participants will receive standard care guided by the results of the validated test (PCR) used for the diagnosis of COVID-19. There are no additional direct benefits or risks. Adverse events are not expected.

Where is the study run from?
IRCCS Sacro Cuore Don Calabria hospital (Italy)

When is the study starting and how long is it expected to run for?
From March 2020 to May 2020

Who is funding the study?
Partially funded by the Italian Ministry of Health (Italy)

Who is the main contact?
Prof Zeno Bisoffi
zeno.bisoffi@sacrocuore.it

Contact information

Type(s)
Scientific

Contact name
Prof Zeno Bisoffi

ORCID ID
https://orcid.org/0000-0001-9530-8742

Contact details
IRCCS Sacro Cuore don Calabria hospital
Via Sempreboni 5
Negrar
Italy
37024
+39 (0)456013326
zeno.bisoffi@sacrocuore.it

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Sensitivity, specificity and predictive values of molecular and serological tests for COVID-19: a longitudinal study in the emergency room

Study objectives

To assess sensitivity, specificity and predictive values of different test methods for the diagnosis of SARS-CoV-2 infection used at the hospital emergency room: five IgG-IgM rapid diagnostic tests (RDT), an ELISA IgA-IgG test, and three Reverse Transcriptase-real-time PCR (RT-PCR) tests, with different gene targets, validated and widely used for diagnosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/04/2020, amendment approved 16/06/2020, Ethics Committee for the Clinical Trials (CESC) of Verona and Rovigo Provinces (AOUI di Verona, Servizio di Farmacia dell'Ospedale, Borgo Trento, P.le Stefani, 1, Verona 37126, Italy; +39 (0)45 8123236; comitatoetico.veronarovigo@aovr.veneto.it; comitatoetico.aovr@pecveneto.it), ref: 19408, amendment ref: 33102

Study design
Single-centre observational prospective diagnostic study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Current interventions as of 25/06/2020:
Patients will be recruited at the participating centre emergency room. They will have nasopharyngeal swabs for PCR and blood taken for serological tests. The assessment will be carried out using the standard, RT-PCR used within the department as the gold standard and compared using the statistical technique of Latent Class Analysis. An exploratory analysis will also be carried out using a Composite Reference Standard (CRS). Participants will then be managed according to the results of the validated PCR (a few hours to have the results). All assessment will occur within the same emergency room visit. There will be no follow up, except for cases of uncertain classification, and for the final outcome that will be recorded for all patients admitted to hospital.

Previous interventions:
Patients will be recruited at the participating centre emergency room. They will have nasopharyngeal swabs for PCR and blood taken for serological tests. The assessment will be carried out using the standard, RT-PCR used within the department as the gold standard and compared using the statistical technique of Latent Class Analysis. An exploratory analysis will also be carried out using a Composite Reference Standard (CRS). Participants will then be managed according to the results of the validated PCR (a few hours to have the results). All assessment will occur within the same emergency room visit. There will be no follow up.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome measure as of 25/06/2020:
Test accuracy for the diagnosis of SARS-CoV-2 infection assessed through comparison against a patient classification made using all the molecular tests and selected clinical variables, using the statistical technique of Latent Class Analysis (LCA) and with clinical reassessment of uncertain cases; the standard molecular test is performed at baseline (upon patient recruitment), while the six serological and two additional molecular (Rt-PCR) tests will be performed on cryopreserved swabs (Rt PCR) and serum specimens (serological tests), after completion of patient recruitment.

Previous primary outcome measure:
Test accuracy for the diagnosis of SARS-CoV-2 infection assessed through comparison against a patient classification using the standard molecular test, performed at baseline (upon patient recruitment) and with clinical reassessment of uncertain cases; and the six serological and three molecular (Rt-PCR) tests, performed on cryopreserved swabs (Rt PCR) and serum specimens (serological tests), after completion of patient recruitment (within 1 h)

Key secondary outcome(s))
Current secondary outcome measures as of 25/06/2020:
Test accuracy of the six serological tests in the subset of patients reporting symptom duration ≥7 days assessed using the standard molecular test, performed at baseline (upon patient recruitment).

Previous secondary outcome measures:
Test accuracy in the subset of patients reporting symptom duration ≥7 days assessed using the standard molecular test, performed at baseline (upon patient recruitment); and the six serological and three molecular (Rt-PCR) tests, performed on cryopreserved swabs (Rt PCR) and serum specimens (serological tests), after completion of patient recruitment (within 1 h)

Completion date
25/05/2020

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Clinical suspicion of COVID-19
3. Consent to participate in the study and to the donation of biological samples given

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
346

Key exclusion criteria
1. Missing or invalid samples

Date of first enrolment
03/04/2020

Date of final enrolment
09/05/2020

Locations

Countries of recruitment
Italy

Study participating centre
IRCCS Sacro Cuore Don Calabria hospital
Via Sempreboni 5
Negrar
Italy
37024

Sponsor information

Organisation
IRCCS Sacro Cuore Don Calabria hospital

Funder(s)

Funder type
Government

Funder Name
Ministero della Salute

Alternative Name(s)

Italian Ministry of Health, Italy Ministry of Health, Ministry of Health of Italy, Ministry of Health - Italy, Ministry of Health, Italy

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (Mendeley Data)

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/09/2020	17/03/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes