

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

Submission date 23/06/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/03/2021	Condition category Respiratory	<input type="checkbox"/> 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet (Italian)

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 measure

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)

Secondary outcome measures

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)

Overall study start date

26/02/2020

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400

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

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Italy

37024

Sponsor information**Organisation**

IRCCS Sacro Cuore Don Calabria hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

www.sacrocuore.it

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**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

25/05/2021

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