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Search for antiviral antibodies in COVID-19 patients' eye secretions

Submission date	Recruitment status	[X] Prospectively registered
22/07/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/07/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/03/2021	Infections and Infestations	

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.

In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of March 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.

Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.

The possibility that SARS-Cov-2, the virus responsible for COVID-19, can enter at the eye level causing local symptoms and potentially spreading the infection through tears (ocular fluids) has been recently investigated. However, there is no information about the body's response against the virus in the eye.

Who can participate?
COVID-19 patients and non-infected subjects.

What does the study involve?
Tears will be collected for analysis by the Schirmer test (a strip of a non-toxic filter paper is placed within the lower eyelid for 5 minutes to collect tears). Patients will be evaluated for the antibody response against the virus at the blood level (IgG and IgM), and for the presence of ocular and respiratory symptoms, to eventually correlate the analyzed parameters.

What are the possible benefits and risks of participating?
There are no particular risks in participating in the study, as the ocular fluid will be collected by a non-invasive Schirmer test.

Where is the study run from?
University of Ferrara (Italy)

When is the study starting and how long is it expected to run for?
May 2020 to December 2020, or until the planned number of 60 subjects will be reached.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Elisabetta Caselli, csb@unife.it

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
544-2020

Study information

Scientific Title
Analysis of the anti-SARS-CoV-2 antibody response in ocular fluid of Covid-19 patients: functional meaning and diagnostic/prognostic perspectives

Acronym
AbOcCov

Study objectives
The possibility that SARS-Cov-2, the β-coronavirus causing COVID-19, can affect the eyes causing local symptoms and potentially transmitting and spreading the infection through ocular fluids has been investigated in the past months. The research has mainly focused on detecting the presence of SARS-Cov-2 genome or infectious particles in ocular secretions, to understand whether SARS-Cov-2-positive subjects could spread the virus not only by respiratory droplets but also via ocular fluids. Almost all studies searched virus RNA genome by molecular RT-PCR assays on ocular swabs. Overall, the frequency of SARS-CoV-2 detection in ocular swabs was very low, and the WHO-China Joint Mission on COVID-19 estimated conjunctival congestion in 0.8% of infected individuals, based on a study on 55,924 laboratory-confirmed cases.
However, there is no information about the local immune response against the virus, which could instead be extremely informative of the virus antigen presentation at the eye level.
The present study was thus aimed to evidence the presence of secretory IgA specifically directed against SARS-CoV-2 virus in the ocular fluids.
We expect that the results can give important information on the local immunity developed at the eye level against the SARS-CoV-2 virus.
Such data could be extremely useful for diagnostic/prognostic purposes, and for epidemiological purposes as well.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/062020, Comitato Etico di Area Vasta Emilia Centro della Regione Emilia-Romagna (Azienda Ospedaliero – Universitaria di Bologna, Policlinico S.Orsola-Malpighi - Via Albertoni, 15 – 40138, Bologna, Italy; no telephone number provided; m.voci@ospfe.it), ref: 544/2020/Oss /AOUFe

Study design
Single-centre observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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

Interventions
The study will recruit symptomatic and asymptomatic COVD-19 patients hospitalized at the University-Hospital in Ferrara (Italy). Control non-infected subjects were enrolled as controls.
The ocular fluids will be collected by Schirmer test.
Each sample will be immediately refrigerated and processed within 1 hour from withdrawal.
Ocular fluids will be examined for:
- the presence and titer of anti-SARS-CoV-2 IgA
- the presence of SARS-CoV-2 RNA genome
- the presence and concentration of pro-inflammatory cytokines associated with the COVID-19 "cytokine storm"
In parallel, patients will be evaluated for the antibody response against the virus at the blood level (IgG and IgM), and for the presence of ocular and respiratory symptoms, to eventually correlate the analyzed parameters.

Intervention Type
Other

Primary outcome measure
Presence and titer of anti-SARS-CoV-2 IgA in ocular fluid collected by Schirmer test at a single time point

Secondary outcome measures
1. Presence of SARS-CoV-2 RNA genome in ocular fluid collected by Schirmer test at a single time point
2. Presence and concentration of pro-inflammatory cytokines associated with the COVID-19 "cytokine storm" in ocular fluid collected by Schirmer test at a single time point
3. Antibody response against the virus at the blood level (IgG and IgM) measured by a blood test at a single time point
4. Ocular and respiratory symptoms recorded by the investigator at a single time point

Overall study start date
20/05/2020

Completion date
31/12/2020

Eligibility

Key inclusion criteria
COVID-19 patient hospitalized at the University-Hospital of Ferrara (Italy)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Total final enrolment
48

Key exclusion criteria
Affected by specific ocular pathologies of infectious or other origin

Date of first enrolment
24/07/2020

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Italy

Study participating centre
University-Hospital of Ferrara
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Sponsor information

Organisation
University of Ferrara

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Sponsor type
University/education

Website
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ROR
https://ror.org/041zkgm14

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-review journal.

Intention to publish date
30/11/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			23/07/2020	No	No
Results article	results	03/11/2020	19/03/2021	Yes	No