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Could different settings of immunodysfunction have an impact on COVID-19 disease burden, case fatality ratio and immune response following COVID-19 disease or vaccination?

Submission date
09/10/2021

Recruitment status
No longer recruiting

Registration date
11/10/2021

Overall study status
Completed

Last Edited
07/12/2022

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The pandemic caused by the new SARS-CoV2 coronavirus identified poses the greatest health challenge of the 21st century. More than one year after its appearance, there is still no treatment capable of inducing a cure, and prospects for controlling the pandemic are based on prevention through vaccination with recently developed vaccines.
In SARS-CoV2 infection, the immune response, clinical evolution, contagiousness, and prognosis seem to be influenced by the presence of immunosuppression (the state in which your immune system is not functioning as well as it should). Vaccine efficacy in immunosuppressed patients has not yet been fully characterized. Immunosuppression seems to be associated with a higher death rate, longer duration of infection, and a longer period of contagiousness, enabling these patients to act as a replicative viral reservoir for long periods of time.
The ongoing mass vaccination campaign against SARS-CoV2 infection provides a unique opportunity to assess vaccine response in immunosuppressed patients, particularly people living with HIV (PLWH) and immune-mediated inflammatory diseases (IMIDs) patients. International recommendations regarding COVID-19 vaccination in immunosuppressed patients have been recently updated, acknowledging the need for a booster dose in these patients. We believe that response to vaccination may be one reliable indicator of the degree of immune dysfunction and may translate the inability to protect against infection. We will combine an infection survey with a study on cellular immunity to further characterize vaccine responsiveness in immunosuppressed patients.

Who can participate?
Adult HIV patients and IMIDs patients on immunosuppressive treatment.

What does the study involve?
Clinical data will be registered (past and present medical history, results of exams, and treatments) by consulting clinical files.
Patients will be asked to attend medical appointments and medical examinations proposed,

including taking blood samples.
Blood samples will be collected on admission and at various times over a 12-18 month period, depending on the date of SARS-CoV2 infection and/or administration of the vaccine(s) against COVID-19.

What are the possible benefits and risks of participating?
This study will not have a direct influence on patients' clinical disease status but will allow us to better understand the SARS-COV2 infection, contributing to the care of future patients and medical investigation.
Taking blood samples may cause discomfort or a slight bruise.
No other invasive interventions will be performed; the standard of care of patients at our hospital will not be affected by this study.

Where is the study run from?
The study is run from the Infectious Diseases and Auto-immune Departments of Centro Hospitalar Universitário Lisboa Central, in collaboration with Instituto Gulbenkian de Ciência.

When is the study starting and how long is it expected to run for?
The study is starting in October 2021 and is expected to run for 12-18 months.

Who is funding the study?
This is an investigator initiated study promoted by the Portuguese public hospital Centro Hospitalar Universitário Lisboa Central.
Roche Diagnostics provided the kits necessary for the determination of serology.
The study on cellular immunity will be done in collaboration with Instituto Gulbenkian de Ciência (Portugal)

Who is the main contact?
Diana Póvoas, diana.silva@chlc.min-saude.pt

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
INV_215

Study information

Scientific Title
Seroepidemiological survey and study of cellular immunity against SARS-CoV2 in immunocompromised patients

Study objectives
Immune response following SARS-CoV2 infection and/or vaccination is influenced by immune dysfunction in immunosuppressed patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/06/2021, Ethics Committee for Health of Central Lisbon University Hospital Centre (Centro Hospitalar Universitário Lisboa Central [CHULC], Rua José António Serrano, 1150-199 Lisbon, Portugal; +351-213514410; comissao.etica@chlc.min-saude.pt), ref: 1073/2021

Study design
Single-centre prospective observational longitudinal study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Influence of different settings of immune dysfunction in immunosuppressed patients on antibody and cellular immune responses following SARS-CoV2 infection and/or COVID-19 vaccination.

Interventions
Vaccines will be administered according to the Portuguese national vaccination plan against COVID-19, the investigation team won't be responsible for decision-making regarding vaccine type and brand, timing, and place of vaccination
Clinical data will be registered (past and present medical history, results of exams, and treatments) by consulting clinical files.
Patients will be asked to attend medical appointments and medical examinations proposed, including taking blood samples.
Blood samples will be collected on admission and at various times over a 12 - 18 month period, depending on the date of SARS-CoV2 infection and/or administration of the vaccine(s) against COVID-19.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Comirnaty® (Pfizer); COVID-19 Vaccine Moderna®; VAXZEVRIA® (AstraZeneca), COVID-19 Vaccine Janssen®

Primary outcome(s)
Determination of antibodies to the SARS-CoV-2 nucleoprotein (N) and spike (S) protein receptor binding domain SARS-CoV2 will be by electrochemiluminescence using Elecsys-N and Elecsys-S (Roche Diagnostics) and these results will be expressed in U/mL, using blood samples collected on admission and at various times over a 12 - 18 month period, depending on the date of SARS-CoV2 infection and/or administration of the vaccine(s) against COVID-19

Key secondary outcome(s))
Using blood samples collected on admission and at various times over a 12 - 18 month period, depending on the date of SARS-CoV2 infection and/or administration of the vaccine(s) against COVID-19:
1. Measurement of SARS-CoV2 specific reactive CD8+ T cell response using spheromers (Mallajosyula V, et al. 2021)
2. Assessment of SARS-CoV-2 specific memory B cells responses through a flow cytometric assay using a combination of fluorescently labeled antigens as probes to track the induction of virus-specific memory B cells in longitudinal peripheral blood mononuclear cell (PBMC) samples (Goel RR, et al. 2021)

Completion date
21/12/2022

Eligibility

Key inclusion criteria
1. Adult patients with HIV infection
2. Adult patients with immune-mediated inflammatory disease on immunosuppressive therapies

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
203

Key exclusion criteria
1. Refusal to give informed consent
2. Contraindication to venipuncture

Date of first enrolment
13/10/2021

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
Portugal

Study participating centre
Centro Hospitalar Universitário Lisboa Central
Rua José António Serrano
Lisbon
Portugal
1150-199

Sponsor information

Organisation
Centro Hospitalar de Lisboa Central

ROR
https://ror.org/00k6r3f30

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Roche Diagnostics

Alternative Name(s)
Roche Diagnostics Corporation

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Portuguese		11/10/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes