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Monitoring of immune responses following COVID-19 infection or vaccination in Bobo-Dioulasso, Burkina Faso

Submission date
31/01/2024

Recruitment status
No longer recruiting

Registration date
23/03/2024

Overall study status
Completed

Last Edited
14/02/2024

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Since December 2019, COVID-19 disease due to the SARS-CoV-2 virus has rapidly spread around the world to become a global pandemic. Today, licensed vaccines against COVID-19 have become one of the best weapons to prevent the disease and its comorbidities. Studies of currently licensed COVID-19 vaccines have shown remarkable efficacy in preventing severe disease. These vaccines are likely to have different immunological effects. However, several unresolved issues are likely to hinder the control of the SARS-CoV-2 pandemic: (i) the impact of the successive emergence of current and future SARS-CoV-2 viral variants of concern with reduced susceptibility to natural or vaccine immunity, (ii) the dynamics and persistence of long-term immune responses, (iii) the impact of geographic and/or genetic context has been shown but not elicited. While effectiveness studies and real-life studies have been conducted mainly in northern countries where vaccine coverage is high, the study of immune response dynamics in West Africa remains unknown and could be different. Burkina Faso has been affected by several waves of COVID-19 with more than 20,000 reported cases and about 4000 deaths. The vaccination campaign started in the country in June 2021, with more than 2 million people vaccinated. The campaign is currently being conducted with different types of vaccines and presents an opportunity to better assess the immune response. This study aims to evaluate the dynamics and persistence of immune response in serum (blood) and mucosal tissue following infection with COVID-19 and after vaccination against COVID-19 in African adults in Bobo-Dioulasso (Burkina Faso).

Who can participate?
Two groups of participants will take part in the study. The first group is composed of previously COVID-19-infected adult patients over 18 years of age, confirmed by PCR or antigenic test previously followed by the COVID-19 medical management team in Bobo-Dioulasso since the beginning of the pandemic. The second group will be composed of adults over 18 years of age who volunteer to receive COVID-19 vaccination as part of the national COVID-19 vaccination program in Burkina Faso.

What does the study involve?
After informed consent, participants will be asked to complete a questionnaire on socio-economic data, risky behaviors, compliance with barrier measures, clinical signs and symptoms, vaccination history, medical history, illnesses, and date of infection for former COVID-19 patients or expected dates of vaccination for volunteers selected for vaccination. Then a screening visit will be scheduled. During the visit a doctor will examine the participant and a blood sample will be collected. Participants will then be followed up after 6 months, 1 year, 18 months and 2 years for the post-infection group, and on day 0, day 28, month 3, month 6 and month 12 for the post-vaccination group.

What are the possible benefits and risks of participating?
This study will make it possible to understand the immune response after infection and after vaccination in Burkina Faso as well as to follow the changes in the immunity provided over time. The inclusion of saliva samples could lead to the establishment of a simple, noninvasive screening method of monitoring a donor's humoral immune response to SARS-CoV-2 and potentially their susceptibility to infection. This will help guide public health interventions. Participants who are monitored will benefit from medical follow-up both after infection and after vaccination. The risks to the safety of study participants are negligible because the vaccines will be administered as part of the COVID-19 vaccination program. On the contrary, the participants will benefit from a medical follow-up unlike those who will not be included in the study. COVID-19 patients will be treated and cared for in accordance with standard practices in Burkina Faso.

Where is the study run from?
Centre Muraz (Burkina Faso)

When is the study starting and how long is it expected to run for?
February 2021 to March 2024

Who is funding the study?
European and Developing Countries Clinical Trials Partnership (Netherlands)

Who is the main contact?
Dr Houreratou Barry, houreratoubarry@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
CM-Inserm-01-2021

Study information

Scientific Title
Monitoring of immune responses in post-SARS-CoV-2-infection and post-vaccination against COVID-19 in Bobo-Dioulasso, Burkina Faso

Study objectives
As this is an exploratory monitoring of the persistence of post-infection antibodies or post-vaccine antibodies, the researchers make no formal assumptions in terms of statistics.

In terms of monitoring in the general population, the hypotheses tested are:
1. The level of CD4+ and CD8+ and CD8+ antibody and lymphocyte responses specific to SARS-CoV-2 are likely to decrease significantly between 6 and 12 months after natural infection and post-vaccination. It is hypothesised that the serum concentration of IgG antibodies decreases after 6 months post-infection and that the persistence of immune memory T is long-lasting
2. For participants who have already been infected, it is hypothesized that pre-vaccine responses ("natural" immunity) will have an impact on vaccine responses
3. Epidemiological evolution (diffusion of variants) could impact the level of immune responses
4. The level of activation/inflammation of the immune system assessed by phenotypic tests and serum biomarker assay could influence the quality/intensity of the immune response

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/10/2021, Comité d'Ethique pour la Recheche en Santé (Ministere de la Santé, Building Lamizana, Ouagadougou, 09 BP 709, Burkina Faso; +226 (0)25 40 26 75; senikouanda@gmail.com), ref: 2021-10-213

Primary study design
Observational

Study design
Prospective cohort study

Study type(s)
Other

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

Interventions
Monitoring of serology and T-cell responses (ancillary study in a small group of volunteers) post-infection of former COVID-19 patients confirmed previously monitored by the Bobo-Dioulasso COVID-19 medical management team coupled with post-vaccination serological monitoring of volunteers selected as part of Burkina Faso's national COVID-19 vaccination program.

There are two groups of distinct participants:
1. A post-infection cohort of patients with a history of COVID-19 confirmed by PCR or antigenic test previously followed by the COVID-19 medical management team in Bobo-Dioulasso since the beginning of the pandemic
2. A post-vaccination cohort of volunteers receiving COVID-19 vaccination as part of the national COVID-19 vaccination program in Burkina Faso

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Several SARS-CoV-2 vaccines

Primary outcome(s)
Serum anti-SARS-CoV-2 IgG concentration measured with Luminex at day 0, day 28, month 3, month 6 and month 12 post-vaccination and month 6, month 12 and month 24 post-infection

Key secondary outcome(s)
1. Serum-neutralizing antibody concentration measured using a luciferase sero-neutralization test at day 0, day 28, month 3, month 6 and month 12 post-vaccination and month 6, month 12 and month 24 post-infection
2. Salivary anti-SARS-CoV-2 IgG concentration measured using Luminex technology at day 0, day 28, month 3, month 6 and month 12 post-vaccination and month 6, month 12 and month 24 post-infection
3. Exposure to helminths assessed by ELISA tests at baseline

An ancillary study with 50 participants per group will assess the cellular immune response (CD4+ and CD8+ T cells) by flow cytometry and cellular phenotyping at day 0, day 28, month 3, month 6 and month 12 post-vaccination and month 6, month 12 and month 24 post-infection

Completion date
30/03/2024

Eligibility

Key inclusion criteria
1. Any former COVID-19 patient over the age of 18 years, with a documented PCR test at most 2 years before recruitment, whether they have been followed on the COVID-19 care site or at home

Or
2. Any adult over the age of 18 years ready to receive any COVID-19 vaccination wishing to take part in the study and residing in Bobo-Dioulasso in Burkina Faso

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
201

Key exclusion criteria
1. Any former patients whose PCR test confirming infection is not documented will be excluded from the post-infection cohort.
2. Anyone who has already received a dose of vaccine at the time of inclusion in the study will not be included in the post-vaccination cohort

Date of first enrolment
21/02/2022

Date of final enrolment
18/08/2022

Locations

Countries of recruitment
Burkina Faso

Study participating centre
Centre Muraz
2054 Avenue Mamadou Konaté
Bobo-Dioulasso
Burkina Faso
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Sponsor information

Organisation
Institut National de Santé Publique du Burkina Faso

Funder(s)

Funder type
Research organisation

Funder Name
European and Developing Countries Clinical Trials Partnership

Alternative Name(s)
The European & Developing Countries Clinical Trials Partnership, The European & Developing Countries Clinical Trials Partnership (EDCTP), European and Developing Countries Clinical Trials, Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaios Clínicos, EDCTP

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Dr Houreratou Barry (houreratou.barry@centre-muraz.bf). All data collected will be anonymous using a unique ID (Participant Identification Number) code for each participant. No personal data to identify the participant will be stored. All study forms will be kept in a locked cabinet or room accessible only to the study team. No information regarding the study or data will be communicated to an unauthorized third party, without the prior written approval of the sponsor.

IPD sharing plan summary
Available on request