ANRS0002S CoviCompare-P

A phase II trial assessing immunogenicity and safety of COVID-19 mRNA Vaccine BNT162b2 in adult volunteers with no history of SARS-CoV-2 infection administered with two doses of vaccine (D1-D29) and in adult volunteers with documented history of SARS-CoV-2 infection (of more than 5 months) administered with only one dose of vaccine.

Sponsor Inserm-ANRS

Start of inclusions **08/03/2021**

Inclusion status Completed

End of study **02/12/2023**

Number of participants **280**

Objectives

Main: To assess the humoral immune response to the COVID-19 mRNA Vaccine BNT162b2 in adult volunteers with or without documented history of SARS CoV-2 infection, 28 days after the first or second injection respectively

Secondary(s) :

1. To characterize humoral immune response induced by BNT162b2 at D29 (group 1); at MX (participants to receive the additional dose), at MX+3d* and MX+15d* (*50% of the participants having received the additional vaccination), at MX+28d (participants having received the additional vaccination) and the durability of the immune response at M6, MX+6months and M24 in the 2 groups (with and without documented history of SARS-CoV-2 infection)
2. To assess and characterise the antigen-specific T cell response
3. To evaluate mucosal immunity
4. To determine the repertoire and polyclonality of the humoral response
5. To compare the different post-vaccination immune responses between groups of young and elderly people and, more generally, to assess the effect of age on markers of immune response.
6. To identify biomarkers predictive of the absence or non-persistence of the humoral response
7. To evaluate clinical safety
8. To collect occurrence of SARS-CoV-2 infection and characterise the parameters of immunity at the time of infection
9. Collecting cases of SARS-CoV-2 infection
10. To biobank biological materials (plasma, serum, PBMC…) to address to other secondary ancillary projects

Exploratory objectives

11. To characterize the memory B and T cell response
12. To characterize the Mucosal immunity (functional study) and evaluate the value of Ultrasensitive IgA in saliva by Photoring assay

Contents

1-Information for participants

A - Overall results of the research

Summary of results: data collection in progress Publication references: data collection in progress

B - Secondary re-use of data and samples

This section concerns participants who have been included in the research and have agreed to the re-use of their data and/or samples. Via its website and this document, the research sponsor informs you of projects relating to the secondary re-use of your data and/or samples.

B1. For the non-initiated or ongoing projects listed below only, you have the option of objecting to the secondary use of your samples and/or data. To do so, you must send an e-mail to the following address dpo@inserm.fr giving the name of the trial and the title of the project for which you are objecting to the re-use of your data and/or samples up to one week before the planned date of completion of the project. Thus, for the project entitled CoviCompare programme: comparative analysis of the humoral, cellular and mucosal immune response in response to different vaccines against COVID-19 in adults - Comparison of Pfizer BNT162b2/Sinopharm BBIBP-CorV vaccines, any objections could be collected until 17/02/2024.

Non-initiated projects :

Project title	CoviCompare programme: Comparative analysis of the humoral, cellular and mucosal immune response to different vaccines against COVID-19 in adults - Comparison of Pfizer BNT162b2/Sinopharm BBIBP-CorV vaccines
Project summary	As the global pandemic caused by the SARS-CoV-2 coronavirus continues, various experimental vaccines are being developed. To prepare future vaccination campaigns as effectively as possible, it is essential to have comparative data between these vaccines. These data will make it possible to determine the durability of the immune protection provided by these vaccines, as well as the possible need for a booster vaccination and its timetable, both for the general population and for more vulnerable populations such as the elderly or people with co-morbidities. The ANRS 0144s CoviCompare Guinée (CC-Guinée) NCT05409300/ and ANRS 0002s CoviCompare-P (CC-P) NCT04824638/ trials were conducted as part of the Covicompare programme initiated in 2020 by the I-REIVAC network (Innovative Clinical Research Network in Vaccinology). Based on data collected during the CC-Guinea and CC-P trials, the present study will compare cellular, humoral and mucosal immune responses induced by the Pfizer (BNT162b2) versus Sinopharm (BBIBP-CorV) vaccine in pre-infected subjects of different age strata over time. The primary vaccination schedules were different in the pre-infected populations of these two trials: one dose for the CC-P trial and two doses for the CC-Guinea trial. Comparisons will be made using data from the following measurement times: - Baseline (first visit before vaccine injection) - Two months after the day of the 1st injection. At this measurement time, a single injection will have been given for CC-P, and two injections will have been given for CC-Guinea. - and finally six months after the first injection. The results of the study will make it possible to better anticipate future epidemic waves by determining the key parameters of future vaccination campaigns, under real-life conditions (subjects already infected), with better protection for elderly subjects, a population that is more vulnerable due to the ageing of the immune system (immunosenescence).

Study population	All pre-infected participants in the ANRS 0002S CoviCompare-P trial who received a primary vaccination dose (group 2) All participants in the ANRS 0144s CoviCompare Guinea trial who received two doses of primary vaccination
Provisional project completion date	Start of data collection: 1er quarter 2024 End of data analysis: 31/12/2024
Data recipients in France	Inserm Unit U1219 (Bordeaux)
Recipient of data abroad	NA
Scientific manager(s)	Professor Odile Launay and Professor Eric Tartour
Identity and data controller	ANRS|MIE
Data and/or sample transfer	Data transfer
Retention period for data and/or samples	Data retained for 5 years and archived for 15 years
Data category	Demographic data (gender, month and year of birth) **Health** data Immunological data
Rights associated with data processing	Information concerning your rights of access, opposition, rectification and limitation as well as your right to erasure is set out in the information leaflet for the ANRS 0002s CoviCompare Pfizer trial.

Projects in progress

Project title	
Project summary	
Project start dates	
Data recipients in France	
Recipient of data abroad	
Identity and data controller	
Data and/or sample transfer	
Retention period for data and/or samples	
Data category	

B2. It is not possible to object to **completed projects.** Completed projects

Project title	
Project summary	
Project start dates	
Data recipients in France	
Recipient of data abroad	
Identity and data controller	
Data and/or sample transfer	
Retention period for data and/or samples	
Data category	
Overall project results	Publication or summary of results