**ANRS 0003S COCOPREV**

*(Information for participants)*

**Title** Prevention of COVID-19 complications in high-risk subjects infected with SARS-CoV-2 and receiving curative treatment. A prospective cohort**.**

| ***Headings*** | **Content** |
|---|---|
| *In a nutshell* | Investigator/Principal Investigator : Dr *Youri Yordanov and Prof Guillaume Martin-Blondel* |
| | Structure/teams :<br>- Saint Antoine Hospital Emergency Department<br>- Department of Infectious and Tropical Diseases, Toulouse University Hospital<br>- IPLESP, Institut Pierre Louis d'Epidémiologie et de Santé Publique - INSERM UMR-S 1136/ Sorbonne Universités<br>- Toulouse Institute of Infectious and Inflammatory Diseases (Infinity)<br>- Virology Laboratory, Hôpital de la Pitié Salpêtrière<br>- Virus and Immunity Unit, Institut Pasteur, CNRS UMR 3569 / Université Paris Cité |
| | Start date/End date 21/09/2021 - 18/12/2023 |
| | Number of participants: 756 |
| | Status: data *under analysis* |
| | Pathology: |
| | Promotion: *Inserm-ANRS MIE* |
| | Funded as part of : CAPNET |
| *The project* | The ANRS 0003S COCOPREV study is a national cohort which aims to study the response to curative treatments developed to reduce COVID-19-related complications in infected patients at risk during the pandemic period. |
| *References of Publications (if any)* | • Martin-Blondel G, Marcelin AG, Soulié C, ....., Carrat F, Yordanov Y. Time to negative PCR conversion amongst high-risk patientswith mild-to-moderate Omicron BA.1 and BA.2 COVID-19 treated with sotrovimab ornirmatrelvir. Clin Microbiol Infect. 2023 Apr;29(4):543.e5-543.e9. doi:10.1016/j.cmi.2022.12.016. Epub 2022 Dec 28. PMID: 36586513; PMCID: PMC9794519.<br>• Martin-Blondel G, Marcelin AG, Soulié C, ....., Liblau R, Carrat F, Yordanov Y; COCOPREV Study Group. Outcome of very high-risk patientsstreated by Sotrovimab for mild-to-moderate COVID-19 Omicron, a prospectivecohort study (the ANRS 0003S COCOPREV study). J Infect. 2022Jun;84(6):e101-e104. doi: 10.1016/j.jinf.2022.04.010. Epub 2022 Apr 7. PMID:35398409; PMCID: PMC8988484.<br>• Bruel T, Vrignaud LL, Porrot F, Staropoli I, Planas D, ....., Dorival C, Molino D, Péré H, Yordanov Y, Simon-Lorière E, Veyer D,Carrat F, Schwartz O, Marcelin AG, Martin-Blondel G; ANRS 0003S CoCoPrev StudyGroup. Sotrovimab therapy elicits antiviral activities against Omicron BQ.1.1and XBB.1.5 in sera of immunocompromised patients. Med. 2023 Oct13;4(10):664-667. doi: 10.1016/j.medj.2023.07.007. PMID: 37837962.<br>• Leducq V, Zafilaza K, Fauchois A, Ghidaoui E, Sayon S, Dorival C, Meledje ML, Lusivika-Nzinga C, Yordanov Y, Martin-Blondel G, Carrat F, Marcelin AG, SoulieC; COCOPREV Study Group. Spike protein genetic evolution in patients at high-risk of severe COVID-19 treated by monoclonal antibodies. J Infect Dis. 2023 Nov23:jiad523. doi: 10.1093/infdis/jiad523. Epub ahead of print. PMID: 37996072 |
| | |
| *Type of study* | National prospective multicentre cohort, non-comparative. |
| *Main objectives* | To assess the clinical course of patients infected with SARS-CoV-2 at high risk of complications and receiving curative treatment. |

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| *Secondary objectives* | • Assess virological progression and its determinants<br>• Assessing secondary complications and their determinants<br>• Assessing tolerance to treatment<br>• Assessing the risk of emergence of resistant variants<br>• Assess the feasibility of early prevention of secondary complications<br>• Assessing the immunological response after treatment and its determinants |
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Contents



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## A - Overall results of the research

Summary of

*The overall results of the research are currently being analysed.*

*Summaries of the articles published are as follows:*

1. *Early administration of nirmatrelvir in high-risk patients, compared with sotrovimab, was associated with faster viral clearance. This may help to reduce transmission and prevent viral resistance. This analysis involved 255 patients included in the study (195 patients treated with Sotrovimab and 60 treated with nirmatrevir/ritonavir).*
2. *Early administration of Sotrovimab to Omicron-infected patients was associated with a low rate of COVID-19-related hospitalisations within one month of treatment, and no deaths. This analysis was performed in 249 patients included in the study (133 patients infected with the Delta variant of SARSCOV-2 and treated with Casirivimab/Imdevimab and 116 patients infected with the Omicron variant and treated with Sotrovimab).*
3. *Administration of 500 mg of sotrovimab induces seroneutralisation and cellular cytotoxicity dependent on antibodies to BQ.1.1 and XBB.1.5. Sotrovimab may therefore remain a therapeutic option against these variants. This analysis was carried out on 80 patients included in the study (67 treated with monoclonal antibodies, including 29 with Sotrovimab, and 13 patients treated with nilmatrevir/ritonavir).*
4. *The likelihood of emerging mutations appearing in response to monoclonal antibodies is significant in treated patients, highlighting the crucial need to study these mutations in depth and assess their impact on patients and on the evolutionary trajectory of SARS-CoV-2. This analysis was performed on 264 patients included in the study and treated with casirivimab/imdevimab, sotrovimab, or tixagevimab/cilgavimab.*

## 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. Through 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 uninitiated or ongoing programmed projects listed below only**, you have the option objecting to the secondary use of your samples and/or data. To do so, please send an e-mail to **dpo@inserm.fr** giving your identity, the name of the trial and the title of the project for which you object to the re-use of your data and/or samples up to one week before the planned date of completion of the project.

Non-initiated programmed projects

| | |
|---|---|
| Project title | |

| | |
|---|---|
| Project summary | |
| Provisional project completion date | |
| 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 | |

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.** You cannot object to **completed projects**.

Completed projects

| | |
|---|---|
| Project title | |
| Project summary | |
| Project start and end 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 |