#36 The SARS-CoV-2 vaccine and enrollment of patients with cancer in Phase I trials: The experience at Institute Gustave Roussy

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BACKGROUND

The outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been associated with a disruption of all components of cancer care from screening, diagnosis, monitoring surveillance, treatment and clinical trial enrollment [1-3].

The COVID-19 associated morbidity and mortality in patients with cancer range from 5% to 61%, in contrast to the 2–3% observed in the general population [4].

Patients with active cancer are therefore a priority population for vaccination. Furthermore, the World Health Organization (WHO) considered cancer patient as priorities for Covid-19 vaccination [5].

Guidelines for Covid-19 vaccination for patients enrolled in phase I trials have been proposed by experts[6]. Some experts suggest to avoid starting investigational medicinal product (IMP) until 2 weeks after the second dose of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) for trial IMPs at risk of cytokine release syndrome.
Patients already enrolled in trial should also be vaccinated, but not the days of IMP injection or during the DLT period [7].

In order to better understand the impact of SARS-CoV-2 vaccination on early phase clinical trials, we collected data of patients treated at the Drug Development Department, at Gustave Roussy.

PATIENTS AND METHODS

We conducted a retrospective chart review, single-center study, to observe the relationship between patients enrolled in a Phase I trial at Gustave Roussy and the vaccination of SARS-CoV-2 between the 4th of January and the 1st of June 2021. Patients were contacted by phone if the information was not available in their medical record.

RESULTS

Between the 4th of January and the 1st of June 2021, 178 patients with cancer were included in a Phase I trial at Gustave Roussy. Out of the 178 patients, data was available for 143 patients.

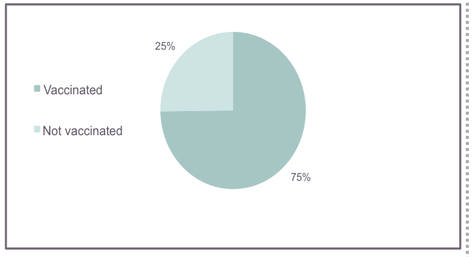

Figure 1: Proportion of vaccination in patients enrolled in early phase clinical trials at DITEP

Out of the 143 patients (100%) where vaccine status was available 107 patients (75%) were vaccinated and 36 patients (25%) were not vaccinated against SARS-CoV-2

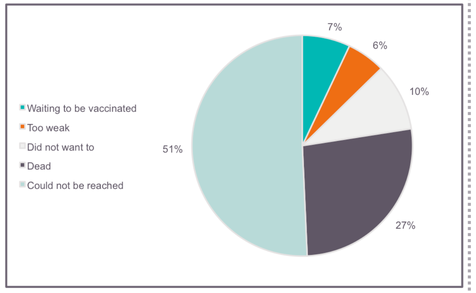

Figure 2: Status of the 71 patients (100%) who were not vaccinated or did not have vaccination status,

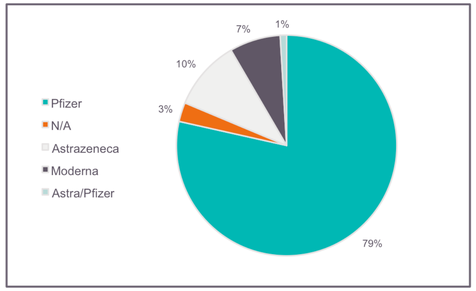

Figure 3: Types of SARS-CoV-2 vaccine received

Out of the 107 patients (100%) who were SARS-CoV-2 vaccinated, 70 patients (65%) were treated by immunotherapy and 23 patients (22%) were in trials with a risk of developing cytokine release syndrome (CRS).

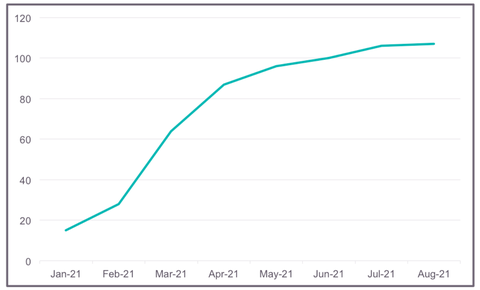

Figure 4: Number of patients vaccinated over time

Most patients were vaccinated in March and April 2021

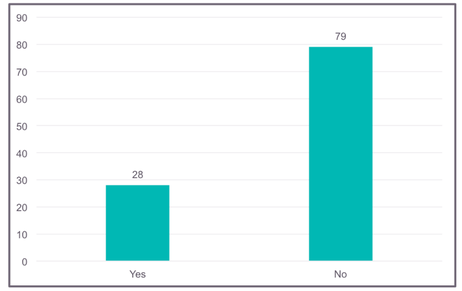

Figure 5: Proportion of patients who had received their first dose in the interval of 21 days before cure 1 to 21 days after the initiation of their IMP

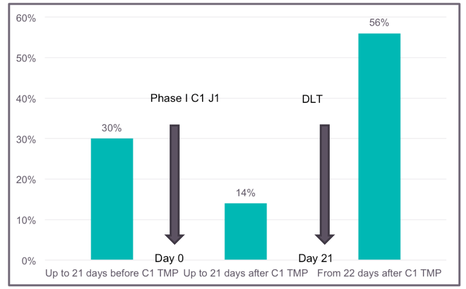

Figure 6: Proportion of patients who received the SARS Cov2 vaccine during screening (3weeks before C1D1) or during the DLT period

Out of these 28 patients, 18 (30%) patients commenced their trial IMP from 3 weeks before and 9 patients (14%) up to 3 weeks after being vaccinated by SARS-CoV-2

Out of the 9 patients, two patients vaccinated with Pfizer-BioNTech developed a pulmonary embolism detected by imaging 48 and 51 days after initiation of the patients' trial IMP. The pulmonary embolisms were not considered to be related to the Pfizer-BioNTech vaccine according to the safety data on the Pfizer-BioNTech vaccine.

Among the 23 patients receiving IMP at risk of CRS, two patients had the SARS-CoV-2 vaccination up to 3 weeks after C1D1. The two patients did not experience any severe infusion related reaction after the vaccination.

REFERENCES

1. Sud A, Torr B, Jones ME, Broggio J, Scott S, Loveday C, et al. Effect of delays in the 2-week-wait cancer referral pathway during the COVID-19 pandemic on cancer survival in the UK: a modelling study. Artic Lancet Oncol [Internet]. 2020 [cited 2021 Sep 13];21:1035–79. Available from: www.gov.uk/guidance/national-
2. Fleury ME, Farner AM, Unger JM. Association of the COVID-19 Outbreak With Patient Willingness to Enroll in Cancer Clinical Trials. JAMA Oncol [Internet]. American Medical Association; 2021 [cited 2021 Sep 13];7:131. Available from: /pmc/articles/PMC7662493/
3. Unger JM, Blanke CD, LeBlanc M, Hershman DL. Association of the Coronavirus Disease 2019 (COVID-19) Outbreak With Enrollment in Cancer Clinical Trials. JAMA Netw Open [Internet]. American Medical Association; 2020 [cited 2021 Sep 13];3:e2010651. Available from: /pmc/articles/PMC7265094/
4. COVID-19 vaccination [Internet]. [cited 2021 Sep 13]. Available from: https://www.esmo.org/covid-19-and-cancer/covid-19-vaccination
5. Framework Goals and Principles at a Glance.
6. Desai A, Gainor JF, Hegde A, Schram AM, Curigiliano G, Pal S, et al. COVID-19 vaccine guidance for patients with cancer participating in oncology clinical trials. Nat Rev Clin Oncol [Internet]. Nature Publishing Group; 2021 [cited 2021 Sep 13];18:1. Available from: /pmc/articles/PMC7957448/
7. Yap TA, Siu LL, Calvo E, Lolkema MP, LoRusso PM, Soria J-C, et al. SARS-CoV-2 vaccination and phase 1 cancer clinical trials. Lancet Oncol [Internet]. Elsevier; 2021 [cited 2021 Sep 13];22:298–301. Available from: http://www.thelancet.com/article/S1470204521000176/fulltext
8. Kelkar AH, Blake JA, Cherabuddi K, Cornett H, McKee BL, Cogle CR. Vaccine Enthusiasm and Hesitancy in Cancer Patients and the Impact of a Webinar. Healthcare [Internet]. Multidisciplinary Digital Publishing Institute (MDPI); 2021 [cited 2021 Sep 13];9. Available from: /pmc/articles/PMC8003419/
9. Curigliano G, Banerjee S, Cervantes A, Garassino MC, Garrido P, Girard N, et al. Managing cancer patients during the COVID-19 pandemic: an ESMO multidisciplinary expert consensus. 2020 [cited 2021 Sep 14]; Available from: https://doi.org/10.1016/j.annonc.2020.07.010

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CONCLUSION

These findings demonstrate SARS-CoV-2 vaccine adherence in patients enrolled in phase I oncological trials. Our study illustrates that patients vaccinated up to 21 days after the initiation of their IMP did not experience any additional adverse events. Therefore, we suggest that phase I trials should not delay the SARS-CoV-2 vaccination in this specific population.

CONTACTS

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