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CoVigi phase IV multicentric trial evaluating COVID-19 vaccination adverse events and immune response dynamics in cancer patients: First results on antibody and cellular immunity

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Background

SARS-CoV-2 infection may be a threat for those undergoing active anti-cancer therapy. We aim to study adverse events, efficacy, and immune response in Covid-19 vaccinated patients focusing on possibly interfering therapy.

Methods

CoVigi is a prospective open-label multicentric phase 4 clinical study (EudraCT 2021-000566-14) enrolling patients on anti-cancer treatment. Vaccines from Pfizer-BioNTech, AstraZeneca, Johnson&Johnson, or Moderna are considered. Data on vaccination side effects, the onset and course of Covid-19, and quantitative analysis of anti-S and anti-N SARS-CoV-2 antibodies (Roche) and SARS-CoV-2 specific cellular response evaluated by IFN-gamma-release assay (Qiagen) and CD69 expression are recorded as follows: at the baseline (prior to the vaccination), prior to the 2nd dose, 4–8 weeks, 3, 6 and 12 months after the first dose.

Results

The trial was initiated on March 22th. As of May 4th, 152 solid cancer and 103 hematooncology patients were enrolled. From preliminary baseline data, 22% of solid cancer and 29% of hematooncology patients had detectable levels of anti-S antibodies with a median of 106 U/ml (range 1.4–3666) and 84 U/ml (range 0.75–2528), respectively ($p = 0.888$). Surprisingly, only 44% solid cancer and 53% of hematooncology patients with detectable antibodies prior to the vaccination referred on covid-19 in medical history. In the Ab-positive cohort, the IFN-gamma level upon both CD4 and CD8 stimulation was 0.04 pg/ml (IQR 0.02–0.13), the CD69 expression on NKT-like cells increased to 10.9% (IQR 6.6–17.3), whereas in the Ab-negative cohort was 0.00 pg/ml (IQR 0.00–0.01 and to 7.5% (IQR 4.0–10.1), respectively ($p < 0.001$ and $p = 0.079$).

Conclusions

Substantial number of cancer patients experienced SARS-CoV-2 infection during active anti-cancer treatment prior to vaccination, often with asymptomatic course. In SARS-CoV-2-immunized patients, we observed SARS-CoV-2 positive cellular response. The preliminary results with dynamics of immune response with 3-month follow-up will be presented at the conference. Acknowledgment: CZECRIN LM2018128, Roche Diagnostics, MMCI00209805, MHCZ/DRO (FNBr, 65269705).

Clinical trial identification

EudraCT 2021-000566-14.

Legal entity responsible for the study

Masaryk University.

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Disclosure

All authors have declared no conflicts of interest.