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Vaccination against SARS-CoV-2 in patients receiving chemotherapy, immunotherapy, or chemo-immunotherapy for solid tumors

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Background

Patients with cancer have an increased risk of complications from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections. Vaccination is recommended, but the impact of chemotherapy and immunotherapy on immunogenicity and safety is still unclear.

Methods

This prospective multicenter non-inferiority trial comprises four cohorts: individuals without cancer (A) and patients with solid tumors who were treated with immunotherapy (B), chemotherapy (C) or chemo-immunotherapy (D). Participants received two mRNA-1273 vaccinations 28 days apart. The primary endpoint was SARS-CoV-2 Spike S1-specific IgG serum antibody response, defined as >10 binding antibody units (BAU)/ml 28 days after the second vaccination. We also assessed the virus neutralizing capacity of these antibodies, SARS-CoV-2 Spike-specific interferon-gamma T cell response, and adverse events.

Results

Of the 791 participants enrolled, 743 were evaluable for the primary endpoint in cohort A (n=240), B (n=131), C (n=229) and D (n=143). A SARS-CoV-2-binding antibody response was found in 100%, 99.3%, 97.4%, and 100% of the participants in cohorts A, B, C, and D, respectively. To discriminate between suboptimal and adequate responders, we defined a cut-off level at 300 BAU/ml, based on neutralizing capacity. The antibody response was considered adequate after the first vaccination in 66.0%, 37.1%, 32.5%, and 33.3% of the participants in cohorts A, B, C, and D, respectively. This raised 28 days after the second vaccination to respectively 99.6%, 93.1%, 83.8%, and 88.8% in cohorts A, B, C, and D. Spike-specific T cell responses were detected in 46.7% of suboptimal and non-responders. No new safety signals were observed.

Conclusions

mRNA-1273 vaccination is safe in the patient populations studied. For each cohort, the proportion of patients with a SARS-CoV-2-binding antibody response after two vaccinations is non-inferior compared to individuals without cancer. However, a significant minority lacks an adequate response. Most patients have an antibody concentration increase after the second vaccination. Therefore, an additional booster may turn inadequate into adequate responders.

Clinical trial identification

NCT04715438.

Legal entity responsible for the study

University Medical Center Groningen, the Netherlands.

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Disclosure

All authors have declared no conflicts of interest.