

## LBA8

### 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.

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