Assessing the immune response to SARS-CoV-2 mRNA vaccines in SPMS patients treated with siponimod (clinical trial)

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Introduction

SARS-CoV-2 mRNA vaccines are a key factor for fighting the COVID-19 pandemic across the globe. However, data are lacking on the efficacy of these vaccines to induce cellular and humoral immune responses in patients with secondary progressive multiple sclerosis (SPMS) on disease-modifying therapies (DMTs) both over time and after a booster vaccination.

Methods

AMA-VACC is prospective, open-label, three-cohort study including 41 multiple sclerosis patients at ten sites in Germany. Cohort 1 receives SARS-CoV-2 mRNA vaccination during continuous siponimod treatment, cohort 2 interrupts siponimod treatment for the purpose of a full vaccination cycle and cohort 3 is vaccinated during continuous treatment with first-line DMTs (dimethylfumarate, glatirameracetate, interferons, teriflunomide) or no current treatment in clinical routine. Development of neutralizing antibodies (primary endpoint) as well as detection of SARS-CoV-2 specific T-cells (secondary endpoint) are assessed after initial and booster vaccination and monitored for up to 6 months.

Results

Results of previous interim analysis showed that the majority of patients treated with siponimod can mount an immune response after SARS-CoV-2 mRNA vaccination. Here, longitudinal data will be presented describing for the first time the level of cellular and humoral immune response for up to 6 months after vaccination and the effect of booster vaccines in siponimod treated patients.

Conclusion

This analysis will provide data on the maintenance of humoral and cellular immune response after SARS-CoV-2 vaccination in siponimod treated patients and enable physicians and patients to make an informed decision on the coordination of SARS-CoV-2 mRNA (booster) vaccination and SPMS treatment.

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