COVID-19 outcomes and vaccination to SARS-CoV-2 in siponimod treated patients: clinical trial and real-world evidence

Authors:

Herbert Schreiber[1], Olaf H. Hoffmann[2], Cordula Weiss[3], Veronika E. Winkelmann[3], Tobias Bopp[4], Tjalf Ziemssen[5]

[1]Neurological Practice Center Ulm, Pfauengasse 8, 89073 Ulm, Germany.

[2]Department of Neurology, St. Josefs-Krankenhaus, Allee nach Sanssouci 7, 14471 Potsdam, Germany; Medizinische Hochschule Brandenburg Theodor Fontane; 16816 Neuruppin, Germany.

[3]Novartis Pharma GmbH, Roonstr. 25, D-90429 Nuernberg, Germany.

[4]Institute for Immunology, University Medical Center of the Johannes Gutenberg-University, Mainz, Germany

[5]Department of Neurology, Center of Clinical Neuroscience, Carl Gustav Carus University Clinic, University Hospital of Dresden, Fetscherstr. 74, 01307, Dresden, Germany.

Introduction

Treatment with S1P-modulators such as siponimod may increase the risk of infection. During the SARS-CoV-2 pandemic, and once vaccines became available, the question arose whether or not patients with Multiple Sclerosis (MS) on disease-modifying therapies (DMTs) would mount a sufficient immune response. Therefore we compared infection dynamics of COVID-19 in MS patients treated with siponimod and how SARS-CoV-2 vaccination was coordinated in a clinical study as well as in real-world setting.

Methods

The two german studies, in which siponimod was prescribed as part of clinical routine were analyzed for SARS-CoV-2 vaccinations and COVID-19 infections. AMA-VACC is an open-label prospective clinical study including 41 MS patients currently treated with siponimod or a first-line DMT, analyzing serum neutralizing antibodies and SARS-CoV-2 specific T-cells after vaccination. In the ongoing non-interventional real-world study AMASIA siponimod patients are followed over 3 years.

Results

Most patients treated with siponimod received an mRNA vaccine in both studies. Final data from the AMA-VACC study indicate that patients treated with siponimod were able to mount an immune response after vaccination. The dynamics of COVID-19 breakthrough infections suggest that infections occurred predominantly during the omicron wave (n=29) after vaccination. Most cases were mild and did not require hospitalization, treatment with siponimod was continued throughout the infection.

Conclusion

COVID-19 infection dynamics in siponimod-treated patients seem similiar in the two studies, reflecting frequency and severity of the SARS-CoV-2 pandemic in the general population. This analysis will support clinicians to make an informed decision about coordinating SARS-CoV-2 mRNA vaccination and MS treatment.

Commented [WC1]: Quick analysis:
Total of 61 Covid-cases
Out of these 31 had proof of vaccination (booster status currently unclear but can be seen when counting vaccination per patient)
Out of 31 vaccinated Covid cases only 2 were severe and 20 matched overall omicron wave (since Dec 2021)

AMA-VACC: 9 innerhalb Omnicron Wave
AMASIA: 20 innerhalb Ominicron Wave