

## **Incidence of COVID-19 in patients with multiple sclerosis who received SARS-CoV-2 vaccines and are under treatment with high-efficacy therapies in Argentina**

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on behalf RelevarEM

**Background:** We aimed to evaluate the incidence of SARS-CoV-2 breakthrough infection and the side effects of SARS-CoV-2 vaccines in people with MS (PwMS) on high-efficacy disease-modifying therapies (DMTs) (HET) included in the national MS registry in Argentina (RelevarEM).

**Methods:** non-interventional, retrospective cohort study that collected information directly from RelevarEM (clinical trials registry number NCTNCT03375177). Adult PwMS who had been treated for at least 6 months with a HET (ocrelizumab, natalizumab, alemtuzumab, cladribine) who had received at least 2 doses of SARS-CoV-2 vaccines available in Argentina were included. Full course of vaccination was considered after the second dose of the corresponding vaccines. A positive COVID-19 case was defined according to the definition established by the Ministry of Health in Argentina. The primary outcome was to assess the incidence of SARS-CoV-2 breakthrough infection in PwMS on HET vaccinated for COVID-19. Clinical activity after the first dose and up to 6 months after full course vaccine was also collected. Cumulative incidence of SARS-CoV-2 infection was reported for the whole cohort by Kaplan Meier survival curves (which is expressed in percentage) as well as incidence density (which is expressed per 10.000 patient/days with 95%CI).

**Results:** 228 PwMS were included. Most frequent first and second dose received was Astra-Zeneca vaccine, followed by Sputnik vaccine. Most frequent HETs used in included patients were cladribine in 79 (34.8%). We found an incidence density of breakthrough COVID-19 infection of  $3.5 \times 10.000$  patients/day (95%CI 2.3-6.7) after vaccination in Argentina. We described the incidence rate after vaccination for every HET used, it being significantly higher for ocrelizumab compared with other HETs ( $p=0.005$ ) Only 5 patients presented a relapse during the follow-up period with no differences regarding the pre-vaccination period.

**Conclusions:** We found an incidence density of breakthrough COVID-19 infection of  $3.5 \times 10.000$  patients/day (95%CI 2.3-6.7) after vaccination in Argentina.