Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Scientific letter

Safety and immunogenicity of cilgavimab-tixagevimab for COVID-19 pre-exposure prophylaxis in immunocompromised patients

Seguridad e inmunogenicidad de cilgavimab-tixagevimab para la profilaxis preexposición frente a la COVID-19 en pacientes inmunodeprimidos

Dear Editor:

Immunisation of immunocompromised patients is currently a health challenge. Not all diseases and treatments affect the immune system in the same way, so the indications for immunisation may vary according to the clinical profile of the patient.[1] In addition, the vaccine response may be impaired and suboptimal in some specific populations.[2] The COVID-19 pandemic has made the need for proper identification of immunocompromised patients and prioritisation of their immunisation visible to authorities and healthcare professionals. In March 2022, the Spanish Ministry of Health published the indications for use of cilgavimab-tixagevimab (Evusheld®), monoclonal antibodies against COVID-19, in order to cover a medical need that had proven insufficient with vaccines.[3]

The aim of this scientific letter is to present the safety and immunogenicity data of cilgavimab-tixagevimab as prophylaxis against COVID-19 in a group of immunocompromised patients. To this end, a descriptive study on the safety and immunogenicity of cilgavimab-tixagevimab was conducted between June and December 2022 in a vaccine unit. Patients included were immunocompromised patients who, according to the document published in March 2022, had IgG S1 < 260 BAU/mL (inadequate response) between 15 and 30 days after receiving the full COVID-19 vaccination course.[3] Drug safety was assessed at 3 time points: +15 min, +24 h and +48 h after administration. In the first 15 min direct observation was carried out, at +24 h and +48 h telephone contact was made. Immunogenicity was assessed at +3 months after cilgavimab-tixagevimab administration by enzyme-linked immunoadsorption assay (ELISA) for the measurement of IgG S1. As a result, a total of 51 immunocompromised patients were candidates. Of these, 38 patients received cilgavimab-tixagevimab (5 patients refused, 6 patients were no longer candidates because they had COVID-19 after serological assessment and, on repeat testing, had IgG S1 > 260 BAU/mL, and 2 were terminally ill). Of the patients receiving cilgavimab-tixagevimab, 57.9% were male and the mean age was 66.26 years (maximum 89 years, minimum 21 years). In terms of clinical profile, 12 patients (31.57%) had received anti-CD20 drugs (7 rituximab and 5 ocrelizumab), 10 (26.31%) had haematological malignancies, 12 (21.37%) were solid organ recipients (10 kidney, one heart and one liver), one patient (2.63%) was haemodialyzed and 3 (7.89%) had autoimmune diseases. Notably, 2 of the patients who received cilgavimab-tixagevimab had COVID-19 after baseline serology and yet had IgG S1 < 260 BAU/mL on repeat serology.

No immediate ADRs were described. Seven ADRs were identified at +24 h (injection site pain in 3 patients, lower limb paraesthesia in one, injection site pruritus in one, acute gastroenteritis in one and acute gastroenteritis at +48 h), flushing in one and acute gastroenteritis in one) and 3 ADRs at +48 h (bronchial exacerbation, pruritic skin lesions on forearms and myalgias); all were reported to the Pharmacovigilance System. Immunogenicity at +3 months could be analysed in 26 of the 38 patients (+3 months had not yet passed in the case of 8 patients at the time of data analysis, one died for reasons unrelated to COVID-19 or the drug, one was lost to follow-up and two were in severe disease). Overall, all patients had IgG S1 > 260 BAU/mL at +3 months of cilgavimab-tixagevimab (46% > 2.080 BAU/mL; 42% between 1001 and 2080 BAU/mL and 12% between 260 and 1000 BAU/mL).

In conclusion, the use of monoclonal antibodies against COVID-19 in immunocompromised individuals is filling a medical need that was previously unmet. The effectiveness of COVID-19 vaccines in some groups of immunocompromised patients has been shown to be limited and other pharmacological alternatives need to be considered.[4] In the group of patients studied, cilgavimab-tixagevimab had a safety profile similar to that reported in previous studies.[5] No ADRs related to cardiovascular events were recorded. Finally, the immunogenicity described in the present paper is in agreement with that described by other authors.[4]

Ethical considerations

The authors declare that they have followed the hospital protocols on the publication of patient data, and that their privacy has been respected.

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Conflict of interest

The authors declare that they have no conflict of interest for the development of this paper.

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