The effectiveness and safety of COVID-19 vaccines has been demonstrated in the pivotal trials that have led to their approval. However, there is no specific information available regarding COVID-19 vaccination in patients with immune-mediated diseases (IMD).

**AIM AND OBJECTIVES**

Evaluate the effectiveness and safety of COVID-19 vaccines in patients with IMD who are being treated with biological drugs (BD).

**MATERIALS AND METHODS:**

- Prospective descriptive observational study of patients with IMD treated with BD.
- Assessing effectiveness: number of patients who became infected with SARS-CoV-2 after vaccination and whether the infection was asymptomatic, with mild symptoms or required hospital admission.
- Assessing safety: standardised interview of adverse reactions observed in the first seven days after COVID-19 vaccination
- Approved by the Ethics Committee of Research with Medicines under code: 2021/435.

**RESULTS:**

106 patients (52.8% female) were included, with a median age of 53 years (21-76). Twenty-two patients (20.75%) were infected after receiving doses of COVID-19 vaccines: 2 after the first dose, 6 after the second dose and 14 after the third dose. No patient required hospital admission.

The most frequent IMD:

The most used BD:

<table>
<thead>
<tr>
<th>Pain at the injection site (79,2%)</th>
<th>Arthralgia (25,5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue (48%)</td>
<td>Fever (21,7%)</td>
</tr>
<tr>
<td>Malaise (42,4%)</td>
<td>Pruritus (11,3%)</td>
</tr>
<tr>
<td>Myalgia (35,8%)</td>
<td>Nausea/vomiting (9,4%)</td>
</tr>
<tr>
<td>Headache (33%)</td>
<td>Lymphadenopathy (9,4%)</td>
</tr>
</tbody>
</table>

**CONCLUSION AND RELEVANCE**

- 79.25% of the patients studied were not infected with SARS-CoV-2 after vaccination.
- Most of the infected patients had mild symptoms and none of them required hospital admission.
- Adverse reactions were similar to those described in the general population, the most frequent being pain at the injection site, fatigue and malaise.
- COVID-19 vaccines were effective and safe in patients with IMD treated with BD included in the study.