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Pfizer-BioNTech COVID-19 vaccine in patients with severe allergies

Vaccination with the Pfizer-BioNTech COVID-19 vaccine [BNT162b2; tozinameran] appears to be relatively safe in patients with a history of severe allergies, according to findings of an Italian study published in *Vaccine*.

This prospective observational study investigated hypersensitivity reactions after administration of BNT162b2 in 6146 employees at San Raffaele Hospital, Milan, Italy, of whom 118 were screened as having a history of severe allergies and were stratified as low-risk, intermediate-risk or high-risk. At-risk patients were followed up for two weeks after each dose of the vaccine.

Overall, 85% of patients with a history of severe allergies experienced at least one adverse event (AE); 14% had a hypersensitivity reaction after the first dose, second dose or both doses of BNT162b2. The most frequent hypersensitivity reactions were skin manifestations. Hypersensitivity reactions were reported in 35%, 10% and 0% of high-risk, intermediate risk and low-risk patients, respectively, and skin manifestations after the first dose were reported in 27%, 4% and 0%, respectively. No anaphylaxis was reported, and the vaccination schedule was completed in all patients. Non-allergic AEs included fever, chills, lymphadenopathy, muscle pain and fatigue.

Hypersensitivity reactions were reported in 0.2% of patients who had no history of severe allergies, and included anaphylaxis grade 4 in one patient (0.016% of total population).

"This evidence confirms that allergy to mRNA-based vaccines has a relatively low prevalence and suggests that a screening protocol based on clinical history might be sufficient to rule out PEG* allergy and enable a safe vaccination in most patients at risk," said the authors. "On the other hand, the occurrence of *de novo* severe reactions in patients with no clear risk highlights the need for further research," they added.

* polyethylene glycol

Yacoub MR, et al. Efficacy of a rational algorithm to assess allergy risk in patients receiving the BNT162b2 vaccine. Vaccine : 28 Sep 2021. Available from: URL: http://doi.org/10.1016/j.vaccine.2021.09.048

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