## Tozinameran

## Hypersensitivity reaction: 30 case reports

In a prospective observational study of 6146 patients, 30 patients [28 women and 2 men] aged 25-66 years were described, who developed hypersensitivity reaction following tozinameran vaccination for prevention of COVID-19 infection [routes and dosages not stated; not all outcomes stated].

The patients received tozinameran [BNT162b2] vaccination for prevention of COVID-19 infection. Prior to vaccination, the patients had completed screening questionnaire for allergic history and stratified into 2 groups including at-risk group and control subject group. Following the vaccination, from the 30 patients, the 12 patients developed immediate hypersensitivity reactions in the form of itching (n=2), dysphonia and cough (n=1), lingual angioedema (n=1), flushing (n=1), itching and rash (n=1), local erythema, itching and labial angioedema (n=1), sensation of throat disclosure and tachycardia (n=1), sensation of throat disclosure and mouth itching (n=1), anaphylaxis (n=1), urticaria and thoracic pain (n=1) or urticaria, labial angioedema and rash (n=1) within 4 hours from the first dose of vaccination; the 12 patients developed delayed hypersensitivity reactions in the form of itching (n=1), pharyngeal discomfort (n=2), rash (n=2), maculopapular rash (n=1) or mild urticaria (n=1) after 4 hours from the first dose of vaccination; while 6 patients did not experience hypersensitivity reaction with the first dose of tozinameran vaccine.

The few of patients received treatment with H1 antihistamines, proton pump inhibitor or glucocorticoids. The hypersensitivity reaction of resolved within 24 hours in 18 patients, and in 6 patients hypersensitivity reaction did not resolve within 24 hours. Thereafter, the 8 patients received prophylactic H1 antihistamines or anti-leukotrienes therapy prior to second dose of vaccination. The 26 patients received second dose of tozinameran. The 6 patients developed immediate hypersensitivity reactions in the form of disphonia, cough, itching, rash, confusion-iching, thoracic pain, tremor, urticaria, angioedema or flushing within 4 hours from the second dose of vaccination, and the 9 patients developed delayed hypersensitivity reactions in the form of skin rash, urticarial, cough, itching, vasculitic rash, diffuse rash or angioedema after 4 hours from the second dose of vaccination; while 11 patients did not experience hypersensitivity reaction with the second dose of tozinameran vaccine. The few of patients required treatment with H1 antihistamines or glucocorticoids. The hypersensitivity reaction of 5 patients resolved within 24 hours, and in 3 patients hypersensitivity reaction did not resolve within 24 hours.

Yacoub M-R, et al. Efficacy of a rational algorithm to assess allergy risk in patients receiving the BNT162b2 vaccine. Vaccine 39: 6464-6469, No. 44, 22 Oct 2021. Available from: URL: http://www.elsevier.com/locate/vaccine 803614982