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Reported rates of CVST due to COVID-19 vaccination rose after publicising these ADRs

Research published in *Drug Safety* shows that fatal adverse reactions to the COVID-19 vaccines, tozinameran [Comirnaty; Pfizer/BioNTech] and AZD-1222 [ChAdOx1 nCov-19/Vaxzevria; AstraZeneca], are rare and that reports of cerebral venous and sinus thrombosis (CVST) increased after publicising CVST as a possible adverse drug reaction (ADR).

The UK-based researchers used publicly-available data from the MHRA, EudraVigilance and the European Centre for Disease Control to estimate reporting rates (number of cases divided by number of administered vaccines) of suspected CVST and retinal vein thrombosis or occlusion ADRs linked to either vaccine that were reported between January 2021 and October 2021. Comparisons were also made of these ADR rates before versus after widespread publicity in 14 March 2021 linking CVST or retinal vein thrombosis (RVT)/occlusion (RVO) with COVID-19 vaccines.

In the UK, the rate for fatal suspected ADRs was 13 cases per million doses of tozinameran and 23 per million doses for AZD-1222. By October 2021, there were 298 reports (29 fatal) of CVST for AZD-1222 and 59 reports (4 fatal) for tozinameran. Respective rates of RVT/RVO were 104 and 33, with none of the AZD-1222 reports and only 2 for tozinameran reported before 14 March. Between 15 March and October 2021 in Europe, reports of CVST rose from 0 to 443 (183 with thrombocytopenia, 72 fatal) for AZD-1222 and from 2 to 315 (9 with thrombocytopenia, 28 fatal) for tozinameran. European cases of RVT/RVO rose from 0 to 168 for AZD-1222 and from 1 to 220 for tozinameran; four of the AZD-1222 and none of the tozinameran cases were associated with thrombocytopenia.

The researchers point out that reports of these ADRs are rare, but the differing rates of events with accompanying thrombocytopenia for the two vaccines "suggests two different mechanisms of thrombosis".

Ferner RE, et al. Spontaneous Reporting to Regulatory Authorities of Suspected Adverse Drug Reactions to COVID-19 Vaccines Over Time: The Effect of Publicity. Drug Safety : 25 Jan 2022. Available from: URL: https://doi.org/10.1007/s40264-021-01138-z

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