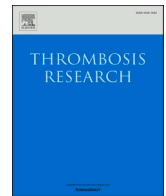




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Hypotheses behind the very rare cases of thrombosis with thrombocytopenia syndrome after SARS-CoV-2 vaccination

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ABSTRACT

As of 4 April 2021, a total of 169 cases of cerebral venous sinus thrombosis (CVST) and 53 cases of splanchnic vein thrombosis were reported to EudraVigilance among around 34 million people vaccinated in the European Economic Area and United Kingdom with COVID-19 Vaccine AstraZeneca, a chimpanzee adenoviral vector (ChAdOx1) encoding the spike protein antigen of the SARS-CoV-2 virus. The first report of the European Medicines Agency gathering data on 20 million people vaccinated with Vaxzevria® in the UK and the EEA concluded that the number of post-vaccination cases with thromboembolic events as a whole reported to EudraVigilance in relation to the number of people vaccinated was *lower* than the estimated rate of such events in the general population. However, the EMA's Pharmacovigilance Risk Assessment Committee concluded that unusual thromboses with low blood platelets should be listed as very rare side effects of Vaxzevria®, pointing to a possible link. The same issue was identified with the COVID-19 Vaccine Janssen (Ad26.COV2.S).

Currently, there is still a sharp contrast between the clinical or experimental data reported in the literature on COVID-19 and the scarcity of data on the unusual thrombotic events observed after the vaccination with these vaccines. Different hypotheses might support these observations and should trigger further *in vitro* and *ex vivo* investigations. Specialized studies were needed to fully understand the potential relationship between vaccination and possible risk factors in order to implement risk minimization strategies.

1. Introduction

As of 4 April 2021, a total of 169 cases of cerebral venous sinus thrombosis (CVST) and 53 cases of splanchnic vein thrombosis were

reported to EudraVigilance among around 34 million people vaccinated in the European Economic Area (EEA) and United Kingdom (UK) with COVID-19 Vaccine AstraZeneca (AZD1222, Vaxzevria®, AstraZeneca, Cambridge, United Kingdom), a chimpanzee adenoviral vector

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