

Advisory for vaccine beneficiaries

Thrombosis and Thrombocytopenia Syndrome (TTS) occurring after administration of COVID-19 vaccine

Reports of rare cases of thrombosis (blood clotting) associated with thrombocytopenia (low platelet counts) – Thrombosis and Thrombocytopenia Syndrome (TTS) - have been reported globally from some countries following the use of some COVID 19 vaccinations particularly AstraZeneca vaccine [Covishield in India] and Johnson & Johnson's Janssen vaccine. The World Health Organization (WHO) and drug regulators of EU, UK and USA are investigating these reports (1, 2). A causal relationship between these rare events has not been established at this time though it is considered to be plausible by WHO (3).

In India, a review of reported 498 serious and severe AEFI cases by National AEFI Committee shows only a few cases clinically compatible with the diagnosis of TTS have been identified. Published scientific literature shows that thromboembolic phenomenon is almost 70% less in South East Asian population compared to those of European descent (4, 5, 6).

Information for vaccine beneficiaries

A vaccine beneficiary vaccinated with any of the COVID-19 vaccines, particularly Covishield and having one or more of the symptoms mentioned below (see BOX) should be suspected to have Thrombosis and Thrombocytopenia Syndrome (TTS). (7)

Symptoms occurring within 20 days after receiving any COVID 19 vaccine (Recipient should report to the health facility where vaccine was administered)

- Shortness of breath
- Chest Pain
- Pain in limbs / pain on pressing the limbs or swelling in the limbs (arm or calf)
- Multiple, pinhead size red spots or bruising of skin in an area beyond the injection site
- Persistent abdominal pain with or without vomiting
- Seizures in the absence of previous history of seizures with or without vomiting
- Severe and persistent headaches with or without vomiting (in the absence of previous history of migraine or chronic headache)
- Weakness/paralysis of limbs or any particular side or part of the body (includes cranial nerve involvements)
- Persistent vomiting without any obvious reason
- Blurred vision/ pain in eyes/Diplopia
- Mental status change / encephalopathy/ depressed level of consciousness
- Any other symptom or health condition which is of concern to the recipient or the family

Contraindications for the administration of COVISHIELD in the context of TTS:

Past history of major venous and arterial thrombosis occurring with thrombocytopenia.

The Ministry of Health and Family Welfare will continue to monitor the safety of all COVID-19 vaccines and promote reporting, investigation and monitoring of suspected adverse events. Covishield, the COVID-19 vaccine continues to have a definite positive benefit-risk profile, with tremendous potential

to mitigate the severity of infections and reduce deaths due to COVID-19 across the world and in India. Over 15.3 crore doses of Covishield vaccine have been administered as of 08th May 2021 in India.

References:

1. EMA Statement: <https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots>
2. UK MHRA statement: <https://www.gov.uk/government/news/uk-regulator-confirms-that-people-should-continue-to-receive-the-covid-19-vaccine-astrazeneca>
3. WHO-GACVS statement of 21 April: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1
4. Lee LH, Gallus A, Jindal R, Wang C, Wu CC. Incidence of Venous Thromboembolism in Asian Populations: A Systematic Review. *Thromb Haemost.* 2017 Dec;117(12):2243-2260. doi: 10.1160/TH17-02-0134. Epub 2017 Dec 6. PMID: 29212112. <https://pubmed.ncbi.nlm.nih.gov/29212112/>
5. White RH, Keenan CR. Effects of race and ethnicity on the incidence of venous thromboembolism. *Thromb Res.* 2009;123 Suppl 4:S11-7. doi: 10.1016/S0049-3848(09)70136-7. PMID: 19303496. <https://pubmed.ncbi.nlm.nih.gov/19303496/>
6. ZAKAI, N.A. and McCLURE, L.A. (2011), Racial differences in venous thromboembolism. *Journal of Thrombosis and Haemostasis*, 9: 1877-1882. <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1538-7836.2011.04443.x>
7. <https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood>