health
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REPUBLIC OF SOUTH AFRICA

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NOTICE: GUIDANCE ON THE MANAGEMENT OF VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT)

There have been reports of vaccine-induced immune thrombotic thrombocytopenia (VITT) associated with COVID-19 vaccines produced by both AstraZeneca/Oxford University (ChAdOx1 CoV-19) and Johnson & Johnson (Ad26.COV2.S). This serious adverse event is **very rare** (reported in less than 1 in 100,000 vaccinated people), but guidance for management of VITT has been recommended by the COVID-19 Guidelines Committee and National Essential Medicines List COVID-19 Therapeutics Subcommittee – see attached Appendix I.

The recommended medicines for the management of VITT, fondaparinux and/or direct-acting oral anticoagulants[1], can be procured by Provinces, through a buy-out process for use by specialists (or in consultation with specialists) at Tertiary and Quaternary hospital level facilities.

Provinces and Healthcare Facilities are requested to distribute and communicate this information in consultation with the Pharmaceutical and Therapeutics Committees.

Kindly share with healthcare professionals, as required.

Comments may be submitted *via* e-mail:
Essential Drugs Programme
E-mail: SAEDP@health.gov.za

Kind regards

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DATE: 13 MAY 2021

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[1] Jacobson et al., Recommendations for the diagnosis and management of vaccine-induced immune thrombotic thrombocytopenia S Afr Med J. Published online 20 April 2021. https://doi.org/10.7196/SAMJ.2021.v111i7.15772

MANAGEMENT OF VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA

The COVID-19 guidelines committee notes the reports of vaccine-induced immune thrombotic thrombocytopenia (VITT) that have followed administration of COVID-19 vaccines produced by both AstraZeneca/Oxford University (ChAdOx1 CoV-19) and Johnson & Johnson (Ad26.COV2.S). Current evidence suggests that this side-effect, while severe, is extremely rare (reported in less than 1 in 100,000 vaccinated people). It appears that the condition may be mediated by platelet factor 4 antibodies, suggesting a similar pathogenesis to a closely-related syndrome, heparin-induced thrombocytopenia (HIT). Apart from this link to HIT, there does not appear to be a connection between the development of VITT and any other previous history of venous or arterial thrombophilia.

The diagnosis of VITT should be considered in the following scenario:

- **Recent COVID-19 vaccination** with either the Johnson & Johnson or AstraZeneca vaccines. This is typically within 3-30 days, although as other cases are identified, this range may change.

AND

- **Platelet count** <150 x10^9/L, or a decrease of ≥50%,

AND/OR

- **Acute thrombosis** – either venous or arterial. As seen in HIT, the venous thromboses may occur in unusual locations, such as the cerebral venous sinuses, the splanchnic veins, or the adrenal veins.

It is essential to manage the patient in consultation with an expert as intravenous immunoglobulin (IVIG) or corticosteroids may be required, and there is a need to balance bleeding and thrombotic risks.

Evidence for the management of this condition is uncertain and is largely extrapolated from the management of HIT. We **suggest** that patients diagnosed with VITT are managed with either[2]:

- Direct-acting oral anticoagulant (i.e. rivaroxaban, apixaban, or dabigatran)
  - e.g. Rivaroxaban, oral, 15 mg 12 hourly for 3 weeks;
  - Followed by 20 mg daily

OR

- Fondaparinux, subcutaneous daily
  - <50 kg: 5 mg once per day
  - 50–100 kg: 7.5 mg once per day
  - >100 kg: 10 mg once per day

Note:

» Avoid platelet transfusions.
» Using heparin or warfarin (in the acute phase) to anticoagulate patients with VITT is **not** recommended.

We acknowledge that fondaparinux and the direct-acting oral anticoagulants are expensive and not included on the national essential medicines list. However, given the life-threatening nature of VITT, and the challenge of vaccine hesitancy, it is recommended that small volumes of one or more of these agents be accessed at tertiary or quaternary facilities through buy-out processes. It is anticipated that fewer than 500 courses of these drugs will be required to treat VITT nationally during the entire vaccine roll-out.

(The guidance in this circular will be included in the next update of the National Department of Health/ National Institute of Communicable Diseases Guidelines for the Clinical Management of Suspected or Confirmed COVID-19 Disease – available from: https://www.knowledgehub.org.za/e-library or https://www.nicd.ac.za/diseases-a-z-index/covid-19/covid-19-guidelines/clinical-management-of-suspected-or-confirmed-covid-19-disease/)

[2] Jacobson et al., Recommendations for the diagnosis and management of vaccine-induced immune thrombotic thrombocytopenia S Afr Med J. Published online 20 April 2021. https://doi.org/10.7196/SAMJ.2021.v111i7.15772