



Patient Information on thrombosis with thrombocytopenia syndrome

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What has been updated:

The newly registered COVID-19 vaccine Spikevax (Moderna) has been included in this advice.

AstraZeneca Vaccine and the COVID-19 vaccination program

The Australian Government receives advice and recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) about the AstraZeneca vaccine.

There has been a link between the AstraZeneca COVID-19 vaccine and a rare condition called thrombosis with thrombocytopenia syndrome (TTS). This condition appears to be more common in younger adults.

Comirnaty (Pfizer) and Spikevax (Moderna) are the preferred COVID-19 vaccines for adults under 60 years of age at this time. However, adults under 60 years of age may still choose to receive the AstraZeneca COVID-19 vaccine if they have weighed up the benefits and the risks. Talk to your doctor or immunisation provider to help inform your decision.

COVID-19 vaccination is recommended for all people aged ≥12 years. The risk of severe illness and death from COVID-19 progressively increases with age in older adults. This means that older adults will have a higher benefit from vaccination.

More information on what this means can be found at www.health.gov.au/covid19-vaccines

What is thrombosis with thrombocytopenia syndrome (TTS)?

This is a rare side effect of the AstraZeneca COVID-19 vaccine. It can be very serious and can cause long-term disability and death. The Pfizer and Moderna COVID-19 vaccines are not associated with a risk of TTS.

The condition causes thrombosis (blood clotting) and thrombocytopenia (low blood platelet counts). It is different from general clotting disorders such as deep vein thrombosis (DVT) or pulmonary embolism (PE). TTS can occur at different parts of the body, including the brain (called cerebral venous sinus thrombosis) and in the abdomen (idiopathic splanchnic vein thrombosis). The low level of blood platelets can potentially cause bleeding.

- Thrombosis is the formation of a blood clot, which prevents blood flowing normally through the body. While thrombosis is usually a normal response to prevent bleeding (e.g. following injury), in this case this process is abnormal.
- Thrombocytopenia is a condition in which you have a low blood platelet count. Platelets (thrombocytes) are blood cells that help blood clot. Platelets stop bleeding by clumping and forming plugs in injured blood vessels.

When does TTS typically occur?

TTS onset occurs around 4 to 42 days (most commonly 4 to 30 days) following vaccination with AstraZeneca.

How common is TTS?

TTS is rare. It is currently estimated to affect about 1-2 per 100,000 people who receive the AstraZeneca COVID-19 vaccine. For those under 60 years of age, the rate is estimated to be higher, about 2-3 per 100,000 people. These estimates will be updated as further information become available.

Are any groups more at risk of TTS?

The rate of TTS reported in Australia and overseas is higher in younger adults and appears more common in women. However, cases have also been reported in men and in older people. It is not yet clear if women are at higher risk.

Based on current information, we have not identified any pre-existing medical conditions that may contribute to developing TTS or make it worse if it occurs.

What symptoms does TTS usually cause?

If you experience the following symptoms after vaccination you should seek medical attention immediately:

- Headache that persists beyond 48 hours after vaccination, or appears later than 48 hours after vaccination:
 - o simple painkillers may alleviate headache initially, but it persists
 - o may be worse when lying down
 - o may be accompanied by nausea and vomiting
- Neurological symptoms such as:
 - o blurred vision
 - o difficulty with speech
 - o drowsiness
 - o seizures
- Shortness of breath
- Chest pain
- Swelling in your leg
- Persistent abdominal (belly) pain
- Tiny blood spots under the skin away from the site of injection.

Do the benefits of the AstraZeneca vaccine outweigh the risk?

Yes. The benefits of vaccination clearly outweigh the risks in many circumstances. This is particularly so for older people who have a higher risk of severe illness or death from COVID-19.

Cases of TTS have occurred in people of all ages. However, the risk of TTS appears to be lower in those aged 60 years and older than in younger adults.

For people under 60 years of age, Pfizer or Moderna COVID-19 vaccines are preferred. However, adults under 60 may still choose to have AstraZeneca vaccine after considering the benefits and risks of vaccination. The risks of dying or having severe disease from COVID-19 are generally lower in healthy younger adults and they have a higher (although still rare) risk of TTS after vaccination compared with older adults.

What if you are aged 60 and under and are booked in to receive your first dose of AstraZeneca?

If you are under the age of 60, Pfizer and Moderna COVID-19 vaccines are preferred for you. If you are younger than 60 you can still choose to have AstraZeneca. Speak with your health professional about what is right for you.

How do people aged under 60 years book an appointment for Pfizer or Moderna? Where are they available?

The COVID-19 vaccination program has been modified in light of the ATAGI advice. More Pfizer and Moderna vaccination sites will become available around the country in line with increasing supplies. You can check your eligibility and where to get a vaccine using the **eligibility checker**.

What if you have received your first dose of AstraZeneca and are due for your second dose?

People of any age without contraindications who have had their first dose of AstraZeneca without any serious adverse events should receive a second dose of the same vaccine. UK data suggests that the risk of TTS is much lower after the second dose, with 44 cases reported to date out of 22.8 million second doses of the AstraZeneca COVID-19 vaccine given. This translates into an estimated rate of 1.9 cases per million second doses (compared to a reported risk of 14.8 cases per million first doses in the UK).

Are there any conditions which increase the risk of TTS?

There is a theoretical concern that a few rare conditions might increase the risk of TTS. These conditions are:

- Cerebral venous sinus thrombosis (a type of blood clot in the brain)
- Heparin-induced thrombocytopenia (a reaction to a medication called heparin)
- Idiopathic splanchnic thrombosis (blood clot in abdominal veins)
- Antiphospholipid syndrome with thrombosis

TTS is different to these certain rare conditions, although there are similarities between TTS and each of these conditions. As a precaution, people with a past history of any of these conditions are recommended to receive the Pfizer or Moderna COVID-19 vaccine over AstraZeneca vaccine at this time. The Pfizer and Moderna vaccines are not associated with TTS.

Is the AstraZeneca vaccine safe in people who have had blood clots in the past?

If you have had other types of blood clots in the past, or if you have risk factors for blood clots, you can still have the AstraZeneca vaccine. There is no evidence that people who have had a past history of other types of blood clots have an increased risk of developing TTS or becoming more ill from it if it occurs.

People with the following conditions can receive the AstraZeneca COVID-19 Vaccine:

- History of blood clots in typical sites
- Increased clotting tendency that is not immune-mediated
- Family history of blood clots
- · History of ischaemic heart disease or stroke
- Current or past thrombocytopenia (low platelet count)
- Those receiving anticoagulation therapy

The overall rate of blood clots has not risen in countries which have extensively used the AstraZeneca vaccine with millions of doses administered. Blood clots occur commonly in the population, and not all blood clots that occur after AstraZeneca COVID-19 will be caused by the vaccine. If you develop a blood clot after vaccination, your doctor can do blood tests to determine the cause.

For more information

Speak to your healthcare professional or vaccination provider if you have further questions about the AstraZeneca vaccine.