# Doctor, can I take Xarelto® instead of warfarin to treat my blood clot caused by triple-positive antiphospholipid antibody syndrome (APLAS)?

No. Patients with a blood clot caused by APLAS who received Xarelto® developed more blood clots that caused strokes and heart attacks than patients who received warfarin. Warfarin remains the best treatment for most patients with APLAS.

## What's the evidence?

**Understanding the problem**

Antiphospholipid antibodies are abnormal proteins produced by the immune system that mistakenly attack proteins that are attached to fats called "phospholipids" found within the lining of blood cells and blood vessels. These antibodies can increase a person's risk of developing a blood clot within arteries and veins and can cause women to have difficulty having successful pregnancies.

There are three different types of antiphospholipid antibodies that can be detected using blood tests. People who have positive tests for all three types of antibodies are called "triple-positive". They have the highest risk of developing blood clots in their arteries and veins as well as the highest risk of having new blood clots despite taking anticoagulants.

People who take warfarin (an anticoagulant) need to have regular blood measurements, called an INR, to ensure the medication dose is correct.  Warfarin may interact with food and lots of other medications. For these reasons, some people dislike taking warfarin. Rivaroxaban (Xarelto®) is an anticoagulant pill that is at least as good as warfarin in preventing blood clots in other conditions. It does not require blood testing and interacts with very few medications, which is why some people prefer to take it instead of warfarin.

The question asked by researchers for this study was, “Is it safe and effective for patients with triple-positive APLAS who have a history of blood clots to take Xarelto® instead of warfarin to prevent new blood clots?”

# The study

**Who?** The study included 120 people aged 18-75 years (average 46 years; 64% female) who had triple-positive APLAS and a history of a blood clot in a vein or artery.

**What?** The study measured the rates of new blood clots, bleeding, and death due to blood clots in patients who received Xarelto® compared with patients who received warfarin.

| Xarelto® | vs | Warfarin |
|---|---|---|
| One pill of rivaroxaban (Xarelto®) 20 mg once a day<br>OR<br>One pill of rivaroxaban (Xarelto®) 15 mg once a day, in patients with kidney disease | | Warfarin, adjusted to maintain a target INR between 2 and 3 |

# What the researchers found

**This study was stopped early because patients who received** Xarelto® **had more new blood clots than patients who received** warfarin**.**

Note: Not all patients with APLAS are triple-positive, and the results of taking Xarelto® in patients who are only positive for 1 or 2 antiphospholipid antibody types are unknown

# Summary of findings

Xarelto® **compared with** warfarin **in patients with triple positive APLAS**

| Outcomes at 20 months (120 patients) | Rate of events with Xarelto® (59 patients) | Rate of events with warfarin (61 patients) | Results |
|---|---|---|---|
| Arterial blood clot (stroke or heart attack) | 12 out of 100 people | 0 out of 100 people | About 12 more people out of 100 had an arterial blood clot while taking Xarelto® |
| Venous blood clot (DVT or PE) | 0 out of 100 people | 0 out of 100 people | No difference |
| Major bleeding | 7 out of 100 people | 3 out of 100 people | No difference* |

| Outcomes at 20 months (120 patients) | Rate of events with Xarelto® (59 patients) | Rate of events with warfarin (61 patients) | Results |
|---|---|---|---|
| Death | 0 out of 100 people | 0 out of 100 people | No difference |

*Although the rates for the 2 groups look different, the differences were not statistically significant—this means that the difference could be due to chance or to the small number of patients studied rather than due to the different treatments.

*This Evidence Summary is based on the following article:*

*Pengo V, Denas G, Zoppellaro G, et al.* ***Rivaroxaban vs warfarin in high-risk patients with antiphospholipid syndrome.*** *Blood. 2018 Sep 27;132(13):1365-1371. doi: 10.1182/blood-2018-04-848333. Epub 2018 Jul 12. PubMed (https://www.ncbi.nlm.nih.gov/pubmed/30002145?dopt=Abstract)*

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# Glossary

| | |
|---|---|
| **antibodies** | protein produced by the immune system to fight infections |
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| **anticoagulant** | medications that prevent blood clots from forming or travelling (aka blood thinner) |
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| **arteries** | blood vessel with muscular walls that carries oxygen-containing blood from the heart to other parts of the body |
| **artery** | blood vessel with muscular walls that carries oxygen-containing blood from the heart to other parts of the body |
| **DVT** | formation of a blood clot within a vein deep within the leg |
| **major bleeding** | serious bleeding (e.g. requiring a visit to the doctor or hospital, an invasive test to find the source of bleeding or a blood transfusion) |

| | |
|---|---|
| **PE** | blood clot(s) that cause obstruction of blood vessels within the lungs (pulmonary artery), after travelling from veins, most commonly within the leg or arm or pelvis |
| **rivaroxaban** | Xarelto® |
| **stroke** | damage to the brain due to lack of blood supply (aka cerebral vascular accident or CVA) |
| **warfarin** | anticoagulant pill that blocks the liver from making normal clotting proteins (the proteins are still made but they don't work); requires blood tests to monitor the effect (aka Coumadin®) |
| **Xarelto®** | rivaroxaban; anticoagulant pill that does not require blood tests to monitor the effect |