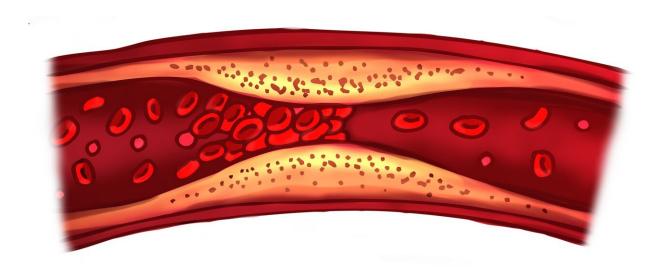


New anti-clotting medication found to reduce bleeding among people with atrial fibrillation

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An experimental anti-clotting medication, abelacimab, significantly reduced bleeding among people with atrial fibrillation (or AFib) who were at risk of stroke, according to <u>results</u> of the AZALEA-TIMI 71 trial, presented today as late-breaking science at the American Heart Association's <u>Scientific Sessions 2023</u>. The meeting, held Nov. 11–13, in Philadelphia, is a premier global exchange of the latest scientific advancements, research and evidence-based clinical practice updates in cardiovascular science.



"This trial confirms the promise of abelacimab to be an incredibly safe anticoagulant for stroke prevention in people with AFib," said study author Christian T. Ruff, M.D., M.P.H., director of general cardiology at Brigham and Women's Hospital in Boston, senior investigator for the TIMI Group and an associate professor of medicine at Harvard Medical School.

The AZALEA-TIMI 71 trial was stopped prematurely on the recommendation of the independent Data Monitoring Committee in September 2023 due to an "overwhelming reduction" in bleeding with abelacimab compared to the anti-clotting medication rivaroxaban.

This is the initial, topline analysis of the Phase 2 of the multi-national trial that compared bleeding occurrence in 1,287 people taking either 90 mg or 150 mg of abelacimab (a factor XI inhibitor) via monthly injection versus people taking 20 mg daily of the oral anti-clotting medication or anticoagulant rivaroxaban. It is the longest and largest trial to-date comparing factor XI inhibitors to the current standard of care use of direct-acting oral anticoagulants.

The analysis found that abelacimab substantially reduced bleeding among people with AFib compared with rivaroxaban, specifically:

- Abelacimab reduced <u>major bleeding</u> that usually required hospitalization and bleeding that required medical attention but not hospitalization by 67% at a dose of 150 mg and 77% at a dose of 90 mg, compared to rivaroxaban.
- At a dose of 150 mg, abelacimab reduced major bleeding by 74% compared to rivaroxaban; and at a dose of 90 mg, it reduced major bleeding by 81%.
- Both doses of abelacimab reduced gastrointestinal bleeding by 93% compared to rivaroxaban.
- Abelacimab was well tolerated with similar rates of adverse



events compared with rivaroxaban.

"Assuming the data from ongoing phase 3 trials confirm the benefit of factor XI inhibitors for <u>stroke prevention</u> in people with <u>atrial fibrillation</u>, it will really be transformative for the field of cardiology," Ruff said. "Our <u>first mission</u> in treating people with AFib is to prevent stroke, and our ability to do this with a remarkably safe anticoagulant such as abelacimab would be an incredible advance."

People with AFib have about five times higher risk of stroke than people without the irregular heart rhythm condition, according to the American Heart Association. Typically, <u>health care professionals</u> will prescribe <u>blood thinners</u> or anticoagulants to reduce the risk of stroke by restricting the body's ability to form blood clots, Ruff said. However, anti-clotting medications include a higher risk for bleeding, which may also be life threatening or result in patients discontinuing treatment, and therefore these issues influence who may safely take anti-coagulants.

Trial details and background:

- Abelacimab is an injectable, monoclonal antibody, categorized as a factor XI inhibitor, that has the potential to prevent the clots that cause strokes and heart attacks while preserving the body's natural ability to repair blood vessels during an injury. This could lower the risk of bleeding for people who take it.
- The study enrolled 1,287 adults across 95 global study sites including the U.S. and Canada, Europe and Asia between March and December 2021 with median follow-up of 1.8 years.
- Participants were 55-years-old and older (44% women) with a history of AFib and who were taking anticoagulants.
- Participants were at moderate to high risk of stroke as determined by history of congestive heart failure, <u>high blood</u> <u>pressure</u>, their age, Type 2 diabetes and <u>stroke</u> and vascular



- disease—which is known as the CHA2DS2-VASc score.
- In a 2021 study, abelacimab was shown to effectively prevent blood clots among people who had knee replacement surgery.

More information: Abelacimab, a Novel Factor XI/XIa Inhibitor, vs Rivaroxaban in Patients with Atrial Fibrillation: Primary Results of the AZALEA-TIMI 71 Randomized Trial. www.abstractsonline.com/pp8/?_...1/presentation/17375

Provided by American Heart Association

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