

## **New study suggests fish oil derivative may benefit heart health**

By Michael Nedelman

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(*CNN*) — New numbers suggest that a purified fish oil derivative, a prescription drug called Vascepa, is more effective at preventing cardiovascular events than previously thought.

The drug lowered the rate of these events in high-risk patients -- including strokes, heart attacks and deaths from cardiovascular causes -- by 30% overall versus placebo, according to a [study](#) published Monday in the Journal of the American College of Cardiology.

This is better than previously thought because because the study authors took into account not just first cardiovascular events as before, but also second, third, fourth events, and so on. Earlier results were [announced](#) by Irish drugmaker Amarin Pharma in September and then in a [study](#) released November in the New England Journal of Medicine.

"By looking only at first events, we underestimate the true underlying treatment benefit offered," study author Dr. Deepak L. Bhatt said in a [statement](#) Monday.

"With this drug, we are not only preventing that first heart attack but potentially the second stroke and maybe that third fatal event," said Bhatt, executive director of interventional cardiovascular programs at Brigham and Women's Hospital and professor of medicine at Harvard Medical School.

According to these latest data on cardiovascular episodes, Vascepa slashed first events by a quarter, second and third events by more than 30%, and later events by almost a half. The researchers estimated that by treating a thousand patients for five years, they could prevent 76 coronary revascularizations, 42 heart attacks, 14 strokes, 16 hospitalizations due to unstable angina and 12 deaths related to cardiovascular causes.

The study was funded by Amarin. The drug was previously [approved](#) by the US Food and Drug Administration in 2012 to lower triglycerides, a type of lipid, in excess of 500 mg/dL.

Vascepa is a prescription drug derived from a single omega-3 fatty acid isolated from fish. Patients received four grams per day, which Bhatt described as the rough equivalent of eating more than 20 servings of fish a week, according to the Monday statement. However, eating that much fish would also add saturated fats and other ingredients to one's diet, the statement followed.

Amarin gave early wind of the drug's positive results in a [September note to investors](#), boosting company shares from \$2.99 to more than \$12. At the time, experts said the initial findings were not widely expected. The science behind fish oil and cardiovascular health has been inconclusive, and many studies have not shown a benefit.

"Fish oil studies have produced ambiguous results, but this component ... carries significant effect," said cardiologist Dr. Russell Luepker, a Mayo professor of public health at the University of Minnesota who was not involved in the trial. He said the latest results show "certainly more clear outcomes than just taking fish oil capsules."

In September, Luepker initially reserved judgment on the drug but now has a more positive view.

"The number of events prevented is not trivial," he said shortly after attending a presentation on the drug at a meeting of the American College of Cardiology on Monday. "It gives more meaning to something that many of us have suspected for years: that triglycerides are important, and treating people that have high triglycerides is a useful thing."

But cardiologist Dr. Rita Redberg raised additional concerns, saying in an email that a number of unanswered questions remain. For example, the most common events in the study were coronary revascularizations -- procedures like stents that bring blood flow back to the heart. However, she said this can be "quite subjective and done at the discretion of the investigator without objective criteria."

She also expressed concerns about how closely involved Amarin was "in all aspects of the study," which may cast "a large shadow of bias," said Redberg, a professor of medicine at the University of California, San Francisco who was also not involved in the trial.

"It is premature to recommend Vascepa," she said. "We should stick with our strong evidence-based recommendation to eat a Mediterranean style diet, including several servings of fish per week, to reduce cardiovascular risk."

Luepker also pointed out the prescription drug can cost in the ballpark of [\\$300](#) per month, which is "not inexpensive," and said it was important to recognize who was represented in the study.

The 8,179 patients in the study had LDL levels in the normal range, controlled by statins, as well as elevated triglycerides. In addition, they either had "established cardiovascular disease," or they had Type 2 diabetes and at least one other cardiovascular risk factor. Patients were followed for a median 4.9 years.

The new study describes the drug as "well tolerated with no significant differences in rates of serious adverse events versus placebo." The researchers did find an increased risk of irregular heartbeat and bleeding, that was not linked to other serious events like stroke.

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Additional questions remain about how the drug actually works. Experts say it's unclear whether the drug prevents cardiovascular events by acting directly on triglycerides or whether they are a marker for some other process going on in our bodies. Or perhaps some combination of the two.

Roughly a quarter of Americans age 20 and older have elevated triglycerides, according to data from the [National Health and Nutrition Examination Survey](#). High triglycerides are associated with an increased risk of cardiovascular disease in combination with low HDL and high LDL, according to the [US Centers for Disease Control and Prevention](#). The agency says lifestyle choices -- including exercise, weight loss, diet and quitting smoking -- can help lower triglycerides.

[Heart disease](#) is the top cause of death in the US, leading to the deaths of more than 600,000 per year.