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NIH stops study of niacin to prevent heart attacks

By LAURAN NEERGAARD, AP Medical Writer – May 26, 2011

WASHINGTON (AP) — A drug that boosts people's good cholesterol didn't go on to prevent heart attacks or strokes, leading U.S. officials to abruptly halt a major study Thursday.

The disappointing findings involve super-strength niacin, a type of B vitamin that many doctors already prescribe as potential heart protection. The failed study marks the latest setback in the quest to harness good cholesterol to fight the bad kind.

"This sends us a bit back to the drawing board," said Dr. Susan Shurin, cardiovascular chief at the National Institutes of Health.

The bad kind of cholesterol, called LDL, is the main source of artery clogs. Popular statin drugs, sold under such names as Zocor and Lipitor, plus generic forms, are mainstays in lowering LDL. Yet many statin users still have heart attacks, because LDL isn't the whole story.

HDL cholesterol, the good kind, helps fight artery build-up by carrying fats to the liver to be disposed of. That's one reason that people with too little HDL also are at risk of heart disease. So scientists are testing whether giving HDL-boosting drugs in addition to statins could offer heart patients extra protection.

The newest study tested Abbott Laboratories' Niaspan, an extended-release form of niacin that is a far higher dose than is found in dietary supplements. The drug has been sold for years, and previous studies have shown it does boost HDL levels. But no one knew if that translated into fewer heart attacks.

Researchers enrolled more than 3,400 statin users in the U.S. and Canada who had stable heart disease and well-controlled LDL, but were at risk because of low HDL levels and too much of a different bad fat, triglycerides. They were given either Niaspan or a dummy pill to add to their daily medicine.

As expected, the Niaspan users saw their HDL levels rise and their levels of risky triglycerides drop more than people who took a statin alone. But the combination treatment didn't reduce heart attacks, strokes or the need for artery-clearing procedures such as angioplasty, the NIH said.

That finding "is unexpected and a striking contrast to the results of previous trials," said Dr. Jeffrey Probstfield of the University of Washington, who helped lead the study.

But it led the NIH to stop the study 18 months ahead of schedule.

Adding to the decision was a small increase in strokes in the high-dose niacin users — 28 among those 1,718 people given Niaspan, compared with 12 among the 1,696 placebo users. The NIH said it wasn't clear if that small difference was merely a coincidence; previous studies have shown no stroke risk from niacin. In fact, some of the strokes occurred after the Niaspan users quit taking that drug.

What's the message for heart patients?

Statin users who have very low LDL levels, like those in this study, don't need an extra prescription for niacin, said Dr. Robert Eckel, a University of Colorado cardiologist and American Heart Association spokesman who wasn't involved with the study.

But it's not clear if niacin would have any effect on people at higher risk or those who don't have a diagnosis of heart disease yet but take niacin as a preventive, said study co-leader Dr. William Boden of the University at Buffalo.

"We can't generalize these findings ... to patients that we didn't study," he said.

Eckel said it's "really hard to envision exactly what's going to happen in physicians' offices" in coming weeks as they discuss niacin with patients. The NIH urged people not to stop high-dose niacin without consulting a doctor.

Nor do the findings end hope that raising HDL eventually will pan out, Eckel said. While two other drugs have failed as well, he is closely watching some much stronger HDL-boosters, including a Merck & Co. drug named anacetrapib, that are under development.

On the Net:

- Background on niacin: <http://tinyurl.com/3vgablq>
- Niaspan: <http://www.niaspan.com/>



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