New drug significantly lowers bad cholesterol

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For many people with high cholesterol, statins serve as the first line of treatment. However, some patients are unable to effectively reduce their low-density lipoprotein cholesterol (LDL cholesterol) or "bad cholesterol" levels with statins, the most commonly used medication to treat high cholesterol, due to their bodies' inability to tolerate or sufficiently respond to the medicine.

Now researchers at Brigham and Women's Hospital have shown that in patients already on a statin, the addition of a new drug, called AMG 145, can reduce LDL cholesterol levels by up to 66 percent after 12 weeks.

The study was presented at the 2012 American Heart Association Scientific Sessions and electronically published in *Lancet* on November 6, 2012.

In a double-blind, dose-ranging, placebo-controlled study, 631 patients ages 18 to 80 years old with high cholesterol on a stable statin dose (with or without ezetimibe) were randomized to receive one of six different AMG 145 dose regimens or matching placebo. The treatments were given subcutaneously (an injection under the skin) every two or every four weeks for a total of twelve weeks.

In participants who received AMG 145 every two weeks, the drug reduced LDL cholesterol in a dose-dependent manner by 42 to 66 percent at the end of twelve weeks compared to placebo.

For those taking AMG 145 every four weeks, the drug reduced LDL

cholesterol in a dose-dependent manner by 42 to 50 percent at the end of twelve weeks compared to placebo. Moreover, just one week after a dose, researchers saw LDL cholesterol reduced by up to 85 percent.

"The observed reductions in LDL cholesterol are extraordinary, especially when one considers that they are seen on top of statin therapy," said Robert Giugliano, MD, BWH Cardiovascular Division, Department of Medicine, investigator for the Thrombolysis in Myocardial Infarction (TIMI) Study Group, and lead study author.

The highest dose given every two weeks also allowed 93.5 percent of patients to achieve the most stringent cholesterol-lowering goals. Furthermore, the researchers noted that there were no serious adverse events that occurred with AMG 145 treatment.

"These data are very exciting and may offer a new paradigm for LDL cholesterol reduction. The next step will be a large-scale, long-term cardiovascular outcomes trial," said Marc Sabatine, MD, chairman of the TIMI Study Group, and senior study author.

AMG 145 is a monoclonal antibody. It binds to a protein that normally shepherds LDL cholesterol receptors for destruction. By blocking that protein, AMG 145 protects the receptors from being destroyed, thereby increasing the number of LDL cholesterol receptors on the surface of the liver that help remove bad cholesterol from the bloodstream.

More information: my.americanheart.org/professio … 6900_SubHomePage.jsp

Provided by Brigham and Women's Hospital

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