

Alternative treatment for cholesterol shows promise

30 March 2014, by Kerry Sheridan

An experimental treatment has shown promise in lowering bad cholesterol, offering hope for people at risk of heart disease but who cannot tolerate drugs known as statins, researchers said Sunday.

The therapy developed by Amgen pharmaceuticals is known as evolocumab. It is a monoclonal antibody that is injected every couple of weeks or once a month, instead of being taken in a daily pill.

Evolocumab is part of a new class of drugs known as PCSK9 inhibitors, which suppress a gene involved with cholesterol regulation in the liver.

Research from two separate phase III trials released at the American College of Cardiology annual meeting showed it was effective in lowering LDL, or [bad cholesterol](#), with few side effects.

The research showed evolocumab lowered cholesterol further than the only other statin-alternative on the market, ezetimibe.

It also lowered LDL in patients who were already taking [statins](#), suggesting the approach could be used as an add-on for patients who need big reductions in their cholesterol but left sickened by intensive doses of statins.

About nine in 10 patients taking evolocumab achieved an LDL [cholesterol](#) level of under 70 mg/dL, the target for people at high risk for [heart disease](#).

Long-term study needed

Reducing LDL is important because too much of it can lead to clogged arteries, raising the risk of heart attack and stroke.

However, the Amgen-funded studies only lasted three months, so longer term data is needed to fully probe the treatment's safety and see whether it works to prevent heart disease over time.

"This is a really important, breakthrough kind of area," said Peter Libby, professor of medicine at Harvard Medical School.

"Ultimately, the proof of the pudding is in the long term outcome studies that show efficacy and show safety," added Libby, who was not involved in the study.

There are also questions on whether this class of drugs may have negative effects on the brain.

The US Food and Drug Administration last month asked pharmaceutical companies Regeneron and Sanofi to assess potential neurocognitive adverse events in their PCSK9 inhibitor, alirocumab, causing jitters among stockholders and raising concerns about the drugs' path to market approval.

The research presented Sunday showed fewer than 10 percent Regeneron experienced side effects such as headache and muscle pain.

"It is well-tolerated in a difficult, high-risk patient population with a clinically unmet need, so we hope this will be a very good option for these patients," said study author Erik Stroes, professor at the Department of Vascular Medicine in Amsterdam's Medical Center.

Statins are currently taken by about 25 million Americans, though recent guidelines have suggested that more than twice that number could benefit from them.

Researchers say about 15 percent of patients are unable to take statins, mainly due to [muscle pain](#) which interferes with their ability to work, climb stairs and exercise.

People who take statins are also at higher risk of developing diabetes.

"Statins are active drugs, they are wonderful drugs,

unless you experience side effects," said Stroes.

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