

Abstract

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Niacin in Patients with Low HDL Cholesterol Levels Receiving Intensive Statin Therapy.

The AIM-HIGH Investigators

BACKGROUND: In patients with established cardiovascular disease, residual cardiovascular risk persists despite the achievement of target low-density lipoprotein (LDL) cholesterol levels with statin therapy. It is unclear whether extended-release niacin added to simvastatin to raise low levels of high-density lipoprotein (HDL) cholesterol is superior to simvastatin alone in reducing such residual risk.

METHODS: We randomly assigned eligible patients to receive extended-release niacin, 1500 to 2000 mg per day, or matching placebo. All patients received simvastatin, 40 to 80 mg per day, plus ezetimibe, 10 mg per day, if needed, to maintain an LDL cholesterol level of 40 to 80 mg per deciliter (1.03 to 2.07 mmol per liter). The primary end point was the first event of the composite of death from coronary heart disease, nonfatal myocardial infarction, ischemic stroke, hospitalization for an acute coronary syndrome, or symptom-driven coronary or cerebral revascularization.

RESULTS: A total of 3414 patients were randomly assigned to receive niacin (1718) or placebo (1696). The trial was stopped after a mean follow-up period of 3 years owing to a lack of efficacy. At 2 years, niacin therapy had significantly increased the median HDL cholesterol level from 35 mg per deciliter (0.91 mmol per liter) to 42 mg per deciliter (1.08 mmol per liter), lowered the triglyceride level from 164 mg per deciliter (1.85 mmol per liter) to 122 mg per deciliter (1.38 mmol per liter), and lowered the LDL cholesterol level from 74 mg per deciliter (1.91 mmol per liter) to 62 mg per deciliter (1.60 mmol per liter). The primary end point occurred in 282 patients in the niacin group (16.4%) and in 274 patients in the placebo group (16.2%) (hazard ratio, 1.02; 95% confidence interval, 0.87 to 1.21; $P=0.79$ by the log-rank test).

CONCLUSIONS: Among patients with atherosclerotic cardiovascular disease and LDL cholesterol levels of less than 70 mg per deciliter (1.81 mmol per liter), there was no incremental clinical benefit from the addition of niacin to statin therapy during a 36-month follow-up period, despite significant improvements in HDL cholesterol and triglyceride levels. (Funded by the National Heart, Lung, and Blood Institute and Abbott Laboratories; AIM-HIGH ClinicalTrials.gov number, NCT00120289 .).

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