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LIPIDS

Novel omega-3 agent reduces residually high triglyceride levels in patients treated with statins

The ANCHOR trial investigators report that a new omega-3 fatty acid drug, AMR101 (Vascepa®, Amarin Pharma Inc., Mystic, CT, USA), safely reduces elevated (≥200 mg/dl and <500 mg/dl) triglyceride levels and other lipid parameters in patients at high cardiovascular risk who are already receiving statin therapy. These results support those of the MARINE study, published in 2011, in which AMR101 was shown to reduce extremely high (≥500 mg/dl and <2,000 mg/dl) triglyceride levels.

Some triglyceride-lowering agents, such as fish oils that contain both eicosapentaenoic acid and docosahexaenoic acid, can cause worrying increases in LDL-cholesterol levels. AMR101 contains >96% pure eicosapentaenoic acid ethyl ester but no docosahexaenoic acid, and so does not raise LDL-cholesterol levels. AMR101 was approved by the FDA for the treatment of hypertriglyceridemia on 26 July 2012.

The phase III ANCHOR trial was conducted over a 12-week period at 97

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centers in the USA. The researchers enrolled 663 adults with hypertriglyceridemia, and 'target' LDL-cholesterol levels (≥40 mg/dl to <100 mg/dl) achieved with ≥4 weeks of atorvastatin, rosuvastatin, or simvastatin therapy. Participants were randomly assigned to either AMR101 4 g per day, AMR101 2 g per day, or a placebo.

At the end of the study, the median placebo-adjusted triglyceride level had decreased by 21.5% and 10.1% in the AMR101 4 g and 2 g groups, respectively. In addition, AMR101 (high dose, low dose) reduced levels of non-HDL cholesterol (13.6%, 5.5%) and apoplipoprotein B (9.3%, 3.8%), and the inflammatory markers lipoprotein-associated phospholipase A_2 (19.0%, 8.0%) and C-reactive protein (high-sensitivity assay; 22.0%, 6.8%). AMR101 was effective irrespective of whether the patient had diabetes mellitus, or the type of statin therapy. The incidence of adverse events did not differ significantly between the three groups, and no such event was deemed to have been caused by the study medication.

The REDUCE-IT trial, in which ~8,000 patients will be enrolled, is currently underway. This study will determine whether AMR101 4 g per day reduces the incidence of cardiovascular events.

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Original article Ballantyne, C. M. *et al*. Efficacy and safety of eicosapentaenoic acid ethyl ester (AMR101) therapy in statin-treated patients with persistent high triglycerides (from the ANCHOR study). *Am. J. Cardiol.* doi:10.1016/j.amjcard.2012.05.031