

STRENGTH:

Cardiovascular Outcomes with Omega-3 Carboxylic Acids (Epanova) in Patients with High Vascular Risk and Atherogenic Dyslipidemia

Purpose: To evaluate the effects of a carboxylic acid formulation of EPA and DHA (omega-3 CA) on clinical outcomes in patients at high cardiovascular risk.

Trial Design: N= 13,078, Phase III Randomized, placebo-controlled, International, multicenter (686 sites in 22 countries) trial. Enrolled statin treated patients with or at high risk for CVD with triglycerides 180-500mg/dL, HDL <42mg/dL(men) or 47mg/dL (women), median follow up 42.0 months. Trial stopped by Data Monitoring Committee for futility after review of 1384 endpoints.

Primary Endpoints: CV death, MI, Stroke, coronary revascularization, or hospitalization for unstable angina.

Primary Endpoint Components and All-Cause Death	Omega-3 CA (N=6539) % of patients	Corn Oil (N=6539) % of patients	HR (95% CI)	P-value
Primary composite MACE	12.0	12.2	0.99 (0.90, 1.09)	0.84
CV Death	3.5	3.2	1.09 (0.90, 1.31)	0.37
Non-fatal MI	3.3	3.5	0.97 (0.81, 1.17)	0.77
Non-fatal stroke	2.2	1.9	1.14 (0.90, 1.45)	0.28
Coronary revascularization	6.3	6.7	0.94 (0.83, 1.08)	0.41
Unstable angina hospitalization	1.3	1.6	0.84 (0.63, 1.12)	0.23
All-cause death	5.7	5.1	1.13 (0.97, 1.31)	0.11

Results: Administration of omega-3 carboxylic acid 4g daily compared with corn oil placebo did not reduce the incidence of major adverse cardiovascular events, despite a 269% increase in plasma EPA levels. There was an increased risk of atrial fibrillation with Omega-3 CA (HR=1.69, CI 1.29-2.21).

