

The Omega-3 fatty acids in Elderly with Myocardial Infarction (OMEMI) trial

Purpose: Determine the clinical effect of n-3 PUFA supplementation in elderly patients with a recent MI.

Trial Design: N=1014, multi-center, placebo-controlled, double-blind clinical trial

Hypothesis: The hypothesis of the OMEMI trial was that daily addition of 1.8 g n-3 PUFA to standard of care secondary prevention in elderly patients who have survived an AMI would reduce the risk of subsequent cardiovascular events during 2 years follow-up.

Primary Endpoints: The primary efficacy outcome was a composite endpoint of non-fatal MI, unscheduled revascularization, stroke, death from any cause or hospitalization for new or worsened heart failure. The primary safety outcome was major bleeding (Bleeding Academic Research Consortium grade >2)

Secondary Endpoints: New onset AF

	N-3PUFA (n=505)	Placebo (n=509)		
Primary Endpoint	N (%)	N (%)	HR [96% CI]	P-value
Composite primary outcome	108 (21.4)	102 (20.0)	1.07 [0.82-1.40]	0.62
Death as first event	20 (4.0)	20 (4.0)	1.01 [0.54-1.88]	0.98
Non-fatal acute myocardial infraction	39 (7.7)	35 (6.9)	1.14 [0.72-1.80]	0.57
Stroke	17 (3.4)	12 (2.4)	1.37 [0.65-2.88]	0.41
Unscheduled revascularization	14 (2.8)	21 (4.1)	0.66 [0.34-1.30]	0.23
Hospitalization for heart failure	20 (4.0)	17 (3.3)	1.19 [0.62-2.26]	0.61
All-cause mortality	28 (5.54)	28 (5.50)	1.01 [0.60-1.71]	0.97
Secondary Endpoint: New onset AF	28 (7.2)	15 (4.0)	1.84 [0.98-3.45]	0.06

Results: Elderly patients with a recent AMI who received 1.8 g of n-3 PUFA did not have a lower incidence of MACE or death than those randomized to placebo after two years of follow-up. Daily supplementation with 1.8 g EPA/DHA for two years in elderly patients with a recent AMI did not reduce the incidence of cardiovascular events or all-cause mortality.

