

VITAL:

Omega-3 Fatty Acid And Vitamin D Supplementation In The Primary Prevention Of Atrial Fibrillation

Purpose: Atrial fibrillation is the most common heart arrhythmia and affects about 33 million people worldwide. Marine omega-3s and Vitamin D are commonly used supplements which have been implicated in upstream biologic processes leading to the development of AF. These investigators hypothesized that long-term administration of these supplements might be effective in the primary prevention of AF.

Trial Design: The VITAL Rhythm Study (NCT02178410) is an ancillary trial of the VITAL trial (NCT01169259) a primary prevention RCT of CVD and cancer with 25,871 men and women in the US. Double-blind, placebo-controlled randomized trial that tested in a 2x2 factorial design daily supplementation with 2000 IU of vitamin D3 and/or 840 mg of omega-3 fatty acids (Omacor 1g/d; 460 mg EPA + 380 mg of DHA).

Inclusion criteria: men (aged 50+ years) and women (aged 55+ years, total n=25,119 in the VITAL Rhythm study), no history of AF, CVD or cancer. Incident AF diagnoses were prospectively ascertained both by participant self-report and linkage to claims data from Centers for Medicare and Medicaid Services (CMS). The analysis was based on intention to treat.

Endpoints Omega-3 FA and Incident AF	EPA/DHA (n=12,542)	Placebo (n=12,577)	Hazard Ratio (95%CI)	P value
Incidence of AF, subtypes of paroxysmal and non-paroxysmal AF.	469	431	1.09 (0.96-1.24)	0.19
Secondary endpoints				
Paroxysmal AF	271	255	1.07 (0.90-1.27)	0.46
Non-Paroxysmal AF	182	164	1.11 (0.90-1.37)	0.32

Endpoints for Vitamin D and Incident AF	Vitamin D (n=12,553)	Placebo (n=12,566)	Hazard Ratio (95% CI)	P value
All Incident AF	469	431	1.09 (0.96-1.25)	0.19
Secondary Endpoints				
Paroxysmal AF	267	259	1.03 (0.87-1.23)	0.71
Non-Paroxysmal AF	188	158	1.20 (0.97-1.48)	0.10

Overall Results: 5.3 years of follow-up, 900 incident AF events in 25,119 for the primary analysis (3.6% of the total cohort). Supplementation with 840mg/day of marine omega-3 fatty acids (EPA/DHA) and or 2,000 IU/day of Vita D compared to placebo, did not reduce or increase incident AF The findings from both analyses do not support the use of supplemental EPA/DHA or Vita D3 for the primary prevention of AF.

