

Abstract

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Dietary supplementation with n-3 polyunsaturated fatty acids and vitamin E after myocardial infarction: results of the GISSI-Prevenzione trial.

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BACKGROUND: There is conflicting evidence on the benefits of foods rich in vitamin E (alpha-tocopherol), n-3 polyunsaturated fatty acids (PUFA), and their pharmacological substitutes. We investigated the effects of these substances as supplements in patients who had myocardial infarction.

METHODS: From October, 1993, to September, 1995, 11,324 patients surviving recent (≤ 3 months) myocardial infarction were randomly assigned supplements of n-3 PUFA (1 g daily, n=2836), vitamin E (300 mg daily, n=2830), both (n=2830), or none (control, n=2828) for 3.5 years. The primary combined efficacy endpoint was death, non-fatal myocardial infarction, and stroke. Intention-to-treat analyses were done according to a factorial design (two-way) and by treatment group (four-way).

FINDINGS: Treatment with n-3 PUFA, but not vitamin E, significantly lowered the risk of the primary endpoint (relative-risk decrease 10% [95% CI 1-18] by two-way analysis, 15% [2-26] by four-way analysis). Benefit was attributable to a decrease in the risk of death (14% [3-24] two-way, 20% [6-33] four-way) and cardiovascular death (17% [3-29] two-way, 30% [13-44] four-way). The effect of the combined treatment was similar to that for n-3 PUFA for the primary endpoint (14% [1-26]) and for fatal events (20% [5-33]).

INTERPRETATION: Dietary supplementation with n-3 PUFA led to a clinically important and statistically significant benefit. Vitamin E had no benefit. Its effects on fatal cardiovascular events require further exploration.

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