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ORIGINAL ARTICLE

[A Correction Has Been Published](#)

n-3 Fatty Acids in Patients with Multiple Cardiovascular Risk Factors

The Risk and Prevention Study Collaborative Group
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BACKGROUND

Trials have shown a beneficial effect of n-3 polyunsaturated fatty acids in patients with a previous myocardial infarction or heart failure. We evaluated the potential benefit of such therapy in patients with multiple cardiovascular risk factors or atherosclerotic vascular disease who had not had a myocardial infarction.

METHODS

In this double-blind, placebo-controlled clinical trial, we enrolled a cohort of patients who were followed by a network of 860 general practitioners in Italy. Eligible patients were men and women with multiple cardiovascular risk factors or atherosclerotic vascular disease but not myocardial infarction. Patients were randomly assigned to n-3 fatty acids (1 g daily) or placebo (olive oil). The initially specified primary end point was the cumulative rate of death, nonfatal myocardial infarction, and nonfatal stroke. At 1 year, after the event rate was found to be lower than anticipated, the primary end point was revised as time to death from cardiovascular causes or admission to the hospital for cardiovascular causes.

RESULTS

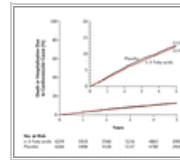
Of the 12,513 patients enrolled, 6244 were randomly assigned to n-3 fatty acids and 6269 to placebo. With a median of 5 years of follow-up, the primary end point occurred in 1478 of 12,505 patients included in the analysis (11.8%), of whom 733 of 6239 (11.7%) had received n-3 fatty acids and 745 of 6266 (11.9%) had received placebo (adjusted hazard ratio with n-3 fatty acids, 0.97; 95% confidence interval, 0.88 to 1.08; P=0.58). The same null results were observed for all the secondary end points.

CONCLUSIONS

In a large general-practice cohort of patients with multiple cardiovascular risk factors, daily treatment with n-3 fatty acids did not reduce cardiovascular mortality and morbidity. (Funded by Società Prodotti Antibiotici and others; ClinicalTrials.gov number,

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FIGURE 1



Kaplan–Meier Curves for Death or First Hospitalization Due to Cardiovascular Cause.

FIGURE 2



Effect of n-3 Polyunsaturated Fatty Acids on the Risk of Death or First Hospitalization Due to Cardiovascular Cause, According to Prespecified Subgroups.

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[Disclosure forms](#) provided by the authors are available with the full text of this article at NEJM.org.

The members of the writing group, who are listed in the Appendix, assume responsibility for the content and integrity of this article.

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SOURCE INFORMATION

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The investigators of the Risk and Prevention Study Collaborative Group are listed in the [Supplementary Appendix](#), available at NEJM.org.

APPENDIX

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