

# The American Journal of Cardiology

Welcome, Mr. Rueda  
[My Subscriptions](#) - [My Alerts](#) - [My Profile](#) - [Logout](#)

Search  for

[Advanced Search](#) - [MEDLINE](#) - [My Recent Searches](#) - [My Saved Searches](#) - [Search Tips](#)

[JOURNAL HOME](#)

[CURRENT ISSUE](#)

[BROWSE ALL ISSUES](#)

[INDEXES](#)

[ARTICLES IN PRESS](#)

[SUPPLEMENTS](#)

[MULTIMEDIA LIBRARY](#)

[SEARCH THIS JOURNAL](#)

[SUBMIT MANUSCRIPT](#)

[JOURNAL INFORMATION](#)

- [Aims and Scope](#)
- [Editorial Board](#)
- [Author Information](#)
- [Advertising Information](#)
- [Abstracting/Indexing](#)
- [Permission to Reuse](#)
- [Contact Information](#)
- [Pricing Information](#)

[SUBSCRIBE TO JOURNAL](#)

[CAREER OPPORTUNITIES](#)

[ENTER CARDIOSOURCE](#)

 [RSS](#)

[Sign Up Now](#)

#### More periodicals:

[FIND A PERIODICAL](#)

[FIND A PORTAL](#)

[GO TO PRODUCT CATALOG](#)



Provided by  
National Library  
of Medicine

**MEDLINE Full Record**

**results list**

## Rationale and design of a randomised controlled clinical trial on supplemental intake of n-3 fatty acids and incidence of cardiac arrhythmia: SOFA.

[Brouwer IA](#), [Zock PL](#), [Wever EF](#), [Hauer RN](#), [Camm AJ](#), [Böcker D](#),

[Otto-Terlouw P](#), [Katan MB](#), [Schouten EG](#)

*Eur J Clin Nutr* 2003; 57:1323-30.

[MEDLINE](#)

[CROSSREF](#)

[CITATION ALERT](#)

[EXPORT CITATION](#)

[EMAIL TO A COLLEAGUE](#)

[RELATED RECORDS](#)

### Abstract

**BACKGROUND:** Evidence from earlier studies indicates that intake of very long-chain n-3 polyunsaturated fatty acids (n-3 PUFA, also named omega-3 fatty acids) as present in fish oil reduces the risk of sudden death. Sudden death forms a major part of mortality from cardiovascular disease and is in most cases a direct consequence of cardiac arrhythmia. n-3 PUFA may exert their protective effect through reducing the susceptibility for cardiac arrhythmia. **OBJECTIVE:** To investigate the effect of n-3 PUFA on the incidence of recurrent ventricular arrhythmia. This paper presents the rationale, design and methods of the Study on Omega-3 Fatty acids and ventricular Arrhythmia (SOFA) and discusses problems encountered in conducting a multicentre clinical trial on food. **DESIGN:** A randomised, parallel, placebo-controlled, double blind intervention study, which obeys the guidelines for Good Clinical Practice. **SETTING:** Multiple cardiology centres in Europe. **SUBJECTS:** A total of 500 patients with an implantable cardioverter defibrillator (ICD). An ICD detects, treats and stores cardiac arrhythmic events in its memory chip. **INTERVENTIONS:** Patients receive either 2 g/day of fish oil, containing approximately 450 mg eicosapentaenoic acid and 350 mg docosahexaenoic acid, or placebo for 12 months. **PRIMARY OUTCOME:** Spontaneous ventricular tachyarrhythmias as recorded by the ICD or all-cause mortality. **CONCLUSION:** SOFA is designed to answer the question whether intake of n-3 PUFA from fish-a regular food ingredient-can reduce the incidence of life-threatening cardiac arrhythmia. If this proves to be true, increasing the intake of n-3 PUFA could be an easy, effective and safe measure to prevent fatal arrhythmia in the general population.

### MeSH

Anti-Arrhythmia Agents; Arrhythmia; Death, Sudden, Cardiac; Defibrillators, Implantable; Double-Blind Method; Fatty Acids, Omega-3; Fish Oils; Humans; Incidence; Multicenter Studies; Patient Compliance; Pilot Projects; Quality Control; Randomized Controlled Trials; Research Design; Sample Size

### CAS Registry Number (Substance Name)

0 (Anti-Arrhythmia Agents), 0 (Fatty Acids, Omega-3), 0 (Fish Oils)

### Author Address

Wageningen Centre for Food Sciences (WCFS), Wageningen, The Netherlands.  
 Ingeborg.Brouwer@staff.NutEpi.wau.nl

### MEDLINE record details

**Publication Type:** Clinical Trial; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't  
**ISSN:** 0954-3007  
**Country:** England  
**Language:** eng  
**Date of Entry:** 20030924  
**Unique Identifier:** 14506496  
**Journal Subset:** IM



Copyright © 2009 Elsevier, Inc. All rights reserved | [Privacy Policy](#) | [Terms & Conditions](#) | [Feedback](#) | [About Us](#) | [Help](#) | [Contact Us](#)