

# N-3 fatty acid supplementation on arrhythmia recurrence in atrial fibrillation

<b>Submission date</b> 30/06/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/03/2009	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
MCT-88068

## Study information

**Scientific Title**  
Randomised trial of the effect of long-chain n-3 polyunsaturated fatty acids on arrhythmia recurrence in atrial fibrillation

**Acronym**

AFFORD

**Study objectives**

Primary hypothesis:

1. N-3 fatty acid supplementation reduces the recurrence of atrial fibrillation (AF) relative to placebo

Secondary hypotheses:

2. N-3 fatty acid supplementation reduces markers of inflammation high sensitivity C-reactive protein [hs-CRP]) relative to placebo

3. N-3 fatty acid supplementation reduces markers of oxidative stress (serum myeloperoxidase) relative to placebo

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Research Ethics Committee of the Montreal Heart Institute/Institut de cardiologie de Montréal approved on the 14th May 2008 (ref: 08-1037)

**Study design**

Double blind (investigator, participant, caregiver, data analyst, outcome assessor) randomised parallel assignment trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Cardiovascular disease/cardiac arrhythmias

**Interventions**

Experimental:

N-3 polyunsaturated fatty acids (fish oil) given daily as 2.4 g eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) daily over a minimum treatment period of 6 months (two capsules twice daily).

Control:

Matching placebo containing safflower oil given daily as two placebo capsules twice daily over a minimum treatment period of 6 months.

**Intervention Type**

Supplement

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

N-3 fatty acid supplementation

**Primary outcome(s)**

Time to first relapse of atrial fibrillation measured from 0 to 6 months minimum, up to 16 months if no AF recurrence between 6 - 16 months.

**Key secondary outcome(s)**

1. High-sensitivity C-reactive protein levels measured at 0 and 6 months
2. Serum myeloperoxidase levels measured at 0 and 6 months

**Completion date**

01/04/2010

**Eligibility**

**Key inclusion criteria**

1. Aged greater than or equal to 18 years, either sex
2. Written informed consent
3. Non-valvular paroxysmal or persistent AF in whom a rhythm control strategy is planned
4. Duration of at least one symptomatic AF episode greater than 10 minutes within the past 6 months
5. Electrocardiogram (ECG) documentation of AF
6. Left ventricular (LV) ejection fraction greater than 40%
7. Normal thyroid stimulating hormone (TSH)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Chronic AF (continuously present for greater than 3 months)
2. Myocardial infarction within the past month prior to selection visit
3. Cardiac or thoracic surgery within the past 3 months or likely to be performed during trial
4. Moderate to severe congestive heart failure (New York Heart Association Functional Class [NHYA FC] III - IV)
5. Left ventricular dysfunction (ejection fraction [EF] less than 40%)
6. Mitral stenosis
7. Moderate to severe mitral insufficiency (Grade 3 - 4/4)
8. AF secondary to an acute reversible condition (untreated or uncontrolled hyperthyroidism,

post-operative AF, fever, anaemia)

9. Need for anti-arrhythmic therapy for a condition other than atrial fibrillation

10. Wolff-Parkinson-White syndrome

11. Any medical condition making compliance with study treatment unlikely

12. Current use of n-3 fatty acid supplements or use within the past 3 months

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

01/04/2010

## Locations

**Countries of recruitment**

Canada

**Study participating centre**

**Institut de Cardiologie de Montréal**

Montreal, Quebec

Canada

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## Sponsor information

**Organisation**

Montreal Heart Institute (Institut de cardiologie de Montréal) (Canada)

**ROR**

<https://ror.org/03vs03g62>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-88068)

# Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration