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

	[X] Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	☐ Results
Condition category	Individual participant data
25/03/2009 Circulatory System	Record updated in last year
	Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Anil Nigam

Contact details

Institut de Cardiologie de Montréal 5000 rue Bélanger est Montreal, Quebec Canada H1T 1C8 +1 514 376 3330 ext. 4033 anil.nigam@icm-mhi.org

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)

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

ΔII

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 H1T 1C8

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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes