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

Submission date	Recruitment status	[X] Prospectively registered
30/06/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/06/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/03/2009	Circulatory System	[ ] 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)

Primary study design
Interventional

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

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
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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