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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

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

Overall study start date
01/09/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
332

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)

Sponsor details
5000 est, rue Bélanger
Montreal, Quebec
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Sponsor type
Research organisation

Website
http://www.icm-mhi.org/en/index.html

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration