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Randomised controlled trial (RCT) of dietary intervention to sustain sinus rhythm in patients following initiation of treatment for atrial fibrillation or flutter

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
26/10/2018

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
RHC11281

Study information

Scientific Title
Randomised controlled trial (RCT) of dietary intervention to sustain sinus rhythm in patients following initiation of treatment for atrial fibrillation or flutter

Study objectives
Effectiveness of policy of providing dietary instruction to eat oil rich fish to maintain sinus rhythm.
To increase sustained sinus rhythm following cardioconversion in patients to be cardioverted for atrial fibrillation or flutter.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Atrial fibrillation and flutter

Interventions
1. Addition of fish oil to the diet
2. Maintenance of normal diet

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary outcome measure will be the number of patients in sustained sinus rhythm for a period of 12 months.

Key secondary outcome(s)
1. Mortality associated with coronary heart disease
2. All mortality
3. Coronary heart disease related morbidity & number of strokes
4. Quality of life assessment
5. Suitability of dietary instructions
6. The patients perception of any change in weekly shopping bills
7. An economic analysis through consultation with a Health Economist.

Completion date
01/07/2002

Eligibility

Key inclusion criteria
Inpatients and outpatients aged 18 years and above, recently diagnosed as having atrial fibrillation or flutter, as determined by electrocardiogram (ECG).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/07/1998

Date of final enrolment
01/07/2002

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wigan & Bolton Health Authority
Wigan
United Kingdom
WN1 1AH

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive North West (UK)

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?
Protocol article	protocol	01/01/2005		Yes	No