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

	Recruitment status	Prospectively registered	
23/01/2004 No	No longer recruiting	[X] Protocol	
Registration date O	verall study status	Statistical analysis plan	
23/01/2004 Co	Completed Condition category	Results	
Last Edited Co		Individual participant data	
	Circulatory System	Record updated in last yea	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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

WN1 1AH

Study participating centre
Wigan & Bolton Health Authority
Wigan
United Kingdom

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