

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/10/2018	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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.

Overall study start date

01/07/1998

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Not provided at time of registration

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

England

United Kingdom

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)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive North West (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/01/2005		Yes	No