A comparison of warfarin and aspirin for stroke prevention in octogenarians in atrial fibrillation study

| Submission date 12/09/2003 | Recruitment status No longer recruiting | Prospectively r |
|----------------------------|---|---|
| Registration date | Overall study status | Protocol Statistical analy |
| 12/09/2003 | Completed | [X] Results |
| Last Edited 06/01/2009 | Condition category Circulatory System | [_] Individual parti |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0164097348

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Study information

Scientific Title

Study objectives To determine whether warfarin or aspirin is better in the prevention of strokes.

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) Not specified

Study type(s) Not Specified

Participant information sheet

Health condition(s) or problem(s) studied Cardiovascular: Stroke

Interventions Wwarfarin or aspirin

Intervention Type Other

Phase Not Specified

Primary outcome measure

- 1. Comparative frequency of embolic events
- 2. Comparative frequency of serious bleeding
- 3. Death
- 4. Refusal to continue
- 5. Adverse events

Secondary outcome measures Not provided at time of registration

Overall study start date 24/04/2001

Completion date 24/04/2003

Eligibility

Key inclusion criteria

200 patients in total aged between 80 and 89 years, with persistant or permanent atrial fibrillation.

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants 200

Key exclusion criteria Not provided at time of registration

Date of first enrolment 24/04/2001

Date of final enrolment 24/04/2003

Locations

Countries of recruitment England

United Kingdom

Study participating centre Royal Hallamshire Hospital NHS Trust Sheffield United Kingdom S10 2JF

Sponsor information

Organisation Department of Health (UK)

Sponsor details Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type Government

Website http://www.doh.gov.uk

Funder(s)

Funder type Government

Funder Name Northern General Hospital NHS Trust (UK)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Details

IPD sharing plan summary Not provided at time of registration

Study outputs

Output type

Date created

Date added

Peer reviewed?

Patient-facing?

Results article results 01/03/2007

Yes

No