Ultra low dose anticoagulation in atrial fibrillation

Submission date 23/01/2004	Recruitment status No longer recruiting	Prospectively registered	
Registration date	Overall study status	 Protocol Statistical analysis plan 	
23/01/2004	Completed	[X] Results	
Last Edited 30/08/2012	Condition category Circulatory System	Individual participant data	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Prof Gareth Beevers

Contact details

University Department of Medicine City Hospital Dudley Rd Birmingham United Kingdom B18 7QH +44 (0)121 507 5080

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers MC7

Study information

Scientific Title

Study objectives

Previous studies have demonstrated increased markers of thrombogenesis in patients with atrial fibrillation (AF), suggesting the presence of a hypercoaguable or prothromobotic state. The objective of this study was to determine the effects of introducing ultra-low-dose warfarin (1 mg), conventional warfarin, and aspirin (300 mg) therapy on thrombogenesis and platelet activation in AF.

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 Heart disease

Interventions

3 treatment arms: 1. Ultra-low-dose warfarin (1 mg) 2. Conventional warfarin 3. Aspirin (300 mg)

Intervention Type Drug

Phase Not Specified Drug/device/biological/vaccine name(s)

Warfarin, aspirin

Primary outcome measure Platelet activation

Secondary outcome measures Not provided at time of registration

Overall study start date 01/04/1994

Completion date 01/04/1996

Eligibility

Key inclusion criteria Patients with atrial fibrillation

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants Not provided at time of registration

Key exclusion criteria Does not match inclusion criteria

Date of first enrolment 01/04/1994

Date of final enrolment 01/04/1996

Locations

Countries of recruitment England

United Kingdom

Study participating centre University Department of Medicine Birmingham United Kingdom B18 7QH

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health 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

NHS Cardiovascular Disease and Stroke National Research and Development Programme (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?
<u>Results article</u>	results	01/08/1996		Yes	No