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A randomised controlled trial of warfarin vs aspirin for atrial fibrillation in an elderly (aged 75 and over) primary care population: Birmingham Atrial Fibrillation Treatment of the Aged study

Submission date 23/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 23/10/2000	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 27/03/2018	**Condition category** Circulatory System	[_] Individual participant data

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
G9900264

Study information

Scientific Title
A randomised controlled trial of warfarin vs aspirin for atrial fibrillation in an elderly (aged 75 and over) primary care population: Birmingham Atrial Fibrillation Treatment of the Aged study

Acronym
BAFTA

Study objectives
To address the question is warfarin better than aspirin in the treatment of patients aged 75 or over identified in general practice with atrial fibrillation? Specifically to test whether:
1. Adjusted dose warfarin (target INR 2.5) will lead to a significantly lower incidence of fatal or disabling stroke (ischaemic or haemorrhagic) or systemic embolus as compared to aspirin (75mg /day)?
2. There will be no significant difference in the incidence of major non-intracranial haemorrhage (a bleeding event requiring hospital admission or causing death) in the two groups?
3. There will be no significant difference in the death rate (all cause) or hospitalisation rate (all cause) in the two groups?
4. A secondary null hypothesis to be tested is that for the patients randomised to warfarin: there will be no difference in the proportion of time spent within the target INR range between patients managed in general practice using near patient testing and computerised decision support software and patients managed by a traditional hospital anticoagulation clinic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Lancaster, 21/03/2013, REC ref: 13/NW/0233

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Atrial fibrillation in primary care

Interventions
Patients will be randomised to:
1. Aspirin 75 mg daily
2. Warfarin, target international normalized ratio (INR) 2.5

Follow-up:
1. Review of GP records at six monthly intervals
2. Annual patient questionnaires
3. Flagging at NHS Central Register
4. Six monthly Review by GP

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Warfarin, aspirin

Primary outcome measure
Fatal or non-fatal disabling stroke (ischaemic or haemorrhagic) or significant systemic embolism

Secondary outcome measures
1. Hospitalisation or death as a result of non-intracranial haemorrhage
2. Death (all cause)
3. Admission to hospital (all cause)
4. Quality of life (SF-12 & Euroqol 5D)
5. Disability (Rankin score)

Overall study start date
01/10/1999

Completion date
01/06/2019

Eligibility

Key inclusion criteria
1. Age 75 or over
2. Non-rheumatic atrial fibrillation confirmed by electrocardiogram (ECG)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
973

Key exclusion criteria
1. Already on warfarin
2. History of major haemorrhage
3. Recent peptic ulcer disease (previous year)
4. Sensitivity to any of the study medications
5. Rheumatic heart disease

Date of first enrolment
01/10/1999

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
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B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details

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Sponsor type
University/education

Website
http://www.bham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results from the BAFTA(2) study will be submitted for planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/02/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/08/2003		Yes	No
Other publications	secondary analysis	25/04/2007		Yes	No
Results article	main results	11/08/2007		Yes	No
Other publications	recruitment analysis	01/12/2010		Yes	No
Results article	results	01/05/2014		Yes	No
HRA research summary			28/06/2023	No	No