

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/03/2018	Condition category Circulatory System	<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

England

Study participating centre

University of Birmingham

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University of Birmingham (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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?
Results article	main results	11/08/2007		Yes	No
Results article	results	01/05/2014		Yes	No
Protocol article	protocol	26/08/2003		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	secondary analysis	25/04/2007		Yes	No
Other publications	recruitment analysis	01/12/2010		Yes	No