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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Jonathan Mant

#### Contact details

Department of Primary Care & General Practice University of Birmingham The Medical School Vincent Drive Edgbaston Birmingham United Kingdom B15 2TT

abc@email.com

## 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 & Eurogol 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

Birmingham United Kingdom B15 2TT

# Sponsor information

## Organisation

University of Birmingham (UK)

## Sponsor details

Edgbaston Birmingham England United Kingdom B15 2TT

-

abc@email.com

## 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