

# Educational intervention for atrial fibrillation

<b>Submission date</b> 24/09/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/09/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Gregory Y H Lip

**Contact details**  
University Department of Medicine  
City Hospital  
Dudley Road  
Birmingham  
United Kingdom  
B18 7QH

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**

TRial of an Educational intervention on patients' knowledge of Atrial fibrillation and anticoagulant therapy, international normalised ratio (INR) control, and outcome of Treatment with warfarin

## **Acronym**

TREAT

## **Study objectives**

The recent National Institute for Health and Clinical Excellence (NICE) guidelines recommend oral anticoagulation among non-valvular atrial fibrillation (NVAf) patients at moderate to high risk of stroke. Among those eligible NVAf patients who agree to take warfarin, the following aims will be explored:

1. The primary endpoint is to examine the effects of an intensive educational intervention on patients international normalised ratio (INR) control within the therapeutic range (INR 2.0 to 3.0)
2. The secondary endpoints will determine the effects of an intensive educational intervention on patients knowledge of, and perceptions of, AF and their beliefs about anticoagulant therapy
3. In addition, the relationship between INR control and the incidence of major and minor bleeding, stroke and thromboembolic events compared to patients receiving usual care will be explored
4. Further, the reasons for persistence with anticoagulant therapy and the reasons for cessation of such treatment will be elicited
5. Finally, a health-care utilisation assessment will be undertaken to determine the costs of the intensive educational intervention compared to usual care

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Black Country Research Ethics Committee, provisional approval as of 1st September 2008 (ref: 08/H1202/133).

## **Study design**

Multicentre randomised controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

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

## **Health condition(s) or problem(s) studied**

## Atrial fibrillation

### Interventions

#### Usual care:

Patients randomised to usual care will be informed about their condition and the need for anticoagulant therapy only. All patients will also receive the standard Yellow book to identify that they are taking OAC therapy. This book contains some basic information pertaining to OAC therapy.

#### Intensive education:

Those in the intensive educational intervention will attend a group session (between 6 - 8 patients for approximately 1 hour) where they will be shown a slide show of information about the need for oral anticoagulants, the risks and benefits associated with OAC therapy, potential interactions with food, drugs, and alcohol, and the importance of monitoring, and control of their INR. This presentation will be given by Professor Lip or his AF research registrar and will be interactive, where the patients are encouraged to ask questions. In addition, patients will also be given an educational booklet.

All patients will be followed up for 12 months.

### Intervention Type

Drug

### Phase

Not Applicable

### Drug/device/biological/vaccine name(s)

Warfarin

### Primary outcome measure

The proportion of time spent in the therapeutic INR range, 2.0 to 3.0; all INRs recorded by the anticoagulation clinic within the first 12 months will be recorded (this will vary for each patient).

### Secondary outcome measures

1. Patients' knowledge and perceptions of AF, questionnaire administered at baseline (time 0), 1, 2, 6, and 12 months
2. Patients' beliefs about their medication, before and after the intervention, questionnaire administered at baseline (time 0), 1, 2, 6, and 12 months
3. The relationship between INR control and patients' experiences of warfarin treatment, the persistence of warfarin therapy, and the incidence of minor and major bleeding, stroke, and thromboembolic events (performed using ancillary analyses, given that the trial is not powered to detect these differences). The number of strokes, bleeding and thromboembolic events will be determined from the computerised clinical information system at the hospital, assessed at 1, 2, 6 and 12 months.
4. A health-economic analysis of the resource utilisation in providing an intensive educational intervention, undertaken at the end of the trial

### Overall study start date

01/01/2009

### Completion date

31/01/2011

## Eligibility

### Key inclusion criteria

1. Atrial fibrillation patients newly referred for, and accepting of, anticoagulant therapy
2. Aged 18 years or older, either sex

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

200

### Key exclusion criteria

1. Aged less than 18 years old
2. Have any contraindication to warfarin or have previously received warfarin
3. Have valvular heart disease
4. Are cognitively impaired
5. Have any disease likely to cause their death within 12 months

### Date of first enrolment

01/01/2009

### Date of final enrolment

31/01/2011

## Locations

### Countries of recruitment

England

United Kingdom

### Study participating centre

University Department of Medicine

Birmingham

United Kingdom

B18 7QH

# Sponsor information

## Organisation

Bayer Plc (UK)

## Sponsor details

c/o Warren Cowell  
Bayer Healthcare Pharmaceuticals  
Hunton House, Highbridge Industrial Estate  
Oxford Road  
Uxbridge  
United Kingdom  
UB8 1HU

## Sponsor type

Industry

## Website

<http://www.bayer.co.uk>

## ROR

<https://ror.org/05emrqw14>

# Funder(s)

## Funder type

Industry

## Funder Name

Bayer Healthcare (UK)

## Alternative Name(s)

BHC

## Funding Body Type

Private sector organisation

## Funding Body Subtype

For-profit companies (industry)

## Location

Germany

# 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?
<a href="#">Protocol article</a>	protocol	20/05/2010		Yes	No
<a href="#">Results article</a>	results	09/09/2013		Yes	No