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Educational intervention for atrial fibrillation

Submission date 24/09/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/12/2008	**Overall study status** Completed	
Last Edited 17/09/2013	**Condition category** Circulatory System	

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
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
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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?
Protocol article	protocol	20/05/2010		Yes	No
Results article	results	09/09/2013		Yes	No