

Educational intervention for atrial fibrillation

Submission date 24/09/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 18/12/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/09/2013	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

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).

Primary study design

Interventional

Study design

Multicentre randomised controlled trial

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre

University Department of Medicine

Birmingham

United Kingdom

B18 7QH

Sponsor information**Organisation**

Bayer Plc (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

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