Assessment of an Education and Guidance programme for Eliquis Adherence in Non-Valvular Atrial Fibrillation.

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Primary:-To assess the impact of educational programme on implementation phase adherence in patients taking apixaban for Stroke Prevention in Non-Valvular Atrial Fibrillation (SPAF) at 24 weeks.Secondary:-To identify predictive risk factors linked…

Ethical review	Not approved
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON38431

Source
ToetsingOnline

Brief title
AEGEAN

Condition

- Cardiac arrhythmias

Synonym
"stroke prevention in Atrial Fibrillation " "stroke prevention in cardiac arrhythmia"

Research involving
Human

Sponsors and support

Primary sponsor: Bristol-Myers Squibb

Source(s) of monetary or material Support: Bristol-Myers Squibb International Corporation

Intervention

Keyword: Education and Guidance, Eliquis Treatment Adherence, Non-Valvular Atrial Fibrillation

Outcome measures

Primary outcome

Primary endpoint:

The percentage of days with a correct execution of the apixaban dosing regimen

during 24 weeks. This endpoint will be compared between the two study groups:

SOC information or additional education.

Secondary outcome

Secondary endpoints:

-Within each study group, percentage of days with a correct execution of the

apixaban dosing regimen during the 12 to 24 weeks period compared with during

the first 12 weeks.

-Adherence to apixaban dosing regimen during the 24 to 48 weeks in continued

additional education group, secondary SOC group and primary SOC group.

-Risk factors indicative of non-adherence at 24 and 48 weeks

-Serious Adverse Events and other AE's, including major bleeding (ISTH)

Study description

Background summary

Adherence to OAC therapy can be challenging because of several reasons specific to management of SPAF. Importance of rigorous patient education have been

recognized. , Specifically for FXa inhibitors such as apixaban, since these treatments do not require routine efficacy monitoring, a key advantage over warfarin, there is a perception amongst some HCPs that long term adherence for apixaban may not be as good as warfarin, the current standard of care. Although FXa inhibitors are superior in efficacy and safety to warfarin, some HCPs may prefer warfarin over an FXa inhibitor because warfarin requires routine monitoring and supervision, thus potentially ensuring greater adherence. The key aim of this clinical study is to investigate the medium term implementation phase adherence (adherence during the implementation phase) of apixaban with education programme on initiation, and whether these additional educational and reminder tools will enhance adherence through innovative technology.
This Phase 4 post marketing authorisation study aims for following:
1. Ensure appropriate usage of apixaban
2. Evaluate value of educational programme
3. Provide information regarding how to improve apixaban adherence for the benefit of patients
4.Support HCP objective of improving patient education

Research Hypothesis:
1. Patients treated with apixaban have a good implementation phase adherence to treatment with standard of care (SOC) patient information on disease and treatment.
2. Implementation phase adherence can be enhanced by additional educational tools, such as educational package, dosing reminders, and virtual clinics.
3. Given the chronic nature of apixaban treatment for stroke prevention in atrial fibrillation (SPAF), persistence of implementation phase adherence to the treatment will improve with adherence tools.
4.Additional educational programme for 24 additional weeks beyond the initial 24 weeks will enhance adherence.

Study objective

Primary:
-To assess the impact of educational programme on implementation phase adherence in patients taking apixaban for Stroke Prevention in Non-Valvular Atrial Fibrillation (SPAF) at 24 weeks.

Secondary:
-To identify predictive risk factors linked to non-adherence in patients treated with apixaban.
-To compare implementation phase adherence to apixaban treatment with secondary SOC versus primary SOC and continued additional educational program.
-To compare implementation phase adherence to apixaban treatment at 12 weeks versus 24 weeks within groups.
-To evaluate impact of educational programme on safety profile of apixaban.

Study design

Multinational, multicentre, randomized, open label clinical trial. Eligible subjects will be randomized 1:1 to receive either SOC information or additional education tools. After the initial 24-weeks primary endpoint period subjects in the group receiving additional education programme will be randomized 1:1 to continue receiving additional education programme or stop and revert to SOC. Patient adherence will be measured using an electronic monitoring device.

Intervention

First 24 weeks:
-group 1 will receive standard information (SOC)
-group 2 will receive additional education programme

Second 24 weeks:
-group 1 will receive standard information (SOC) again
-50% of group 2 will stop with the additional education programme and will receive standard information (SOC)
-the other 50% will continue with the additional education programme

Study burden and risks

The subjects are indicated for the treatment with apixaban. Apixaban is registered in the EU for the use of Prevention of Stroke in Non-Valvular Atrial Fibrillation, of which the side effects are described in the SmPC. The most important side effect is bleeding. The intervention of this study is or standard information or additional education programme without any expected risks. It may enhance adherence in patients using apixaban, important for the efficacy and safety of the medication as it is for longterm use.

Contacts

Public
Bristol-Myers Squibb

Chaussée de la Hulpe 185
Bruxelles B-1170
BE
Scientific
Bristol-Myers Squibb

Chaussée de la Hulpe 185
Bruxelles B-1170

BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Signed written informed consent
-Patients (from18 years old) with diagnosed non-valvular AF and eligible for OAC therapy
-Presence of at least one of the following risk factors for stroke: prior stroke or TIA, Age >74, hypertension, diabetes mellitus, symptomatic heart failure
-must be able to self-administer treatment
-Either VKA treated or VKA naive. VKA-treated patients must have received the VKA treatment for more than 3 months. VKA-naive patients must not have received VKA treatment for more than 30 days within the last 12 months.
-Patients previously treated with ASA for stroke prevention are allowed
-Patients with screening Mini-mental state examination score (MMSE) more than 24 (out of 30).
-Acceptable method of contraception/negative pregnancy test

Exclusion criteria

-Atrial fibrillation or flutter due to reversible causes
-Clinically significant mitral stenosis
-Cardiac valvular disease requiring surgery
-Conditions other than AF that require chronic anticoalgulation (see also section 3.4. of the Protocol)
-Patients with serious bleeding in the last 6 months or with lesion or high risk of bleeding
-Persistent, uncontrolled hypertension
-Active infective endocarditis
-Hepatic disease associated with coagulopathy and clinically relevant bleeding risk
-Active alcohol or drug abuse or psychological reason that makes the study participation

impractical
-Severe co-morbid condition with life expectancy < 1 year
-Severe renal insuffiency calculated by Cockrof-Gault or undergoing dialysis
-Allergy or adverse reaction to Apixaban
-Women who are pregnant or breast feeding
- Women of child bearing potential who are unwilling to meet the study requirements for pregnancy testing or are unwilling / unable to use acceptable method to avoid pregnancy (as per section 3.3.3. of the Protocol)
-Other:
as per section 3.3.2. 6) and 7)
Prohibited and/or restricted treatments as per section 3.4.1. of the protocol

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Eliquis
Generic name:	apixaban
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	24-10-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Not approved Date:	21-11-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2013-000055-41-NL
CCMO	NL45162.068.13