

Role of a Web-Based Interactive Patient-Professional Support System (WIPPS) in the adherence of the Novel Oral Anti-Coagulants: a randomized controlled trial.

Published: 12-11-2013

Last updated: 24-04-2024

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

Summary

ID

NL-OMON38596

Source

ToetsingOnline

Brief title

WIPPS to Comply

Condition

- Cardiac arrhythmias

Synonym

atrial fibrillation, heart arrhythmia

Research involving

Human

Sponsors and support

Primary sponsor: stichting Begeleide Zelfzorg

Source(s) of monetary or material Support: Ministerie van OC&W, Bayer

Intervention

Keyword: Novel Oral Anti-Coagulants, Patient adherence, Rivaroxaban, Web Based Interactive Patient-Professional Support (WIPPS) system

Outcome measures

Primary outcome

Primary outcome is the percentage of compliant patients. Compliance of individual patients is usually reported as the percentage of the prescribed doses of the medication actually taken by the patient over a specified period

Compliance in the trial will be measured by The Medication Possession Rate (MPR). The MPR is calculated by dividing the number of days for which medication has been supplied by the number of days between refills at the pharmacist. As patients can pick up medication before they run out, compliance can be over 100%. A patient is considered compliant or adherent when $MPR = 80\% - 120\%$.

Secondary outcome

Patient satisfaction. This will be measured, using a custom-made questionnaire, regarding aspects of care tailored to patients using anticoagulant medication.

Study description

Background summary

With the arrival of new oral anticoagulants - i.e. oral factor Xa inhibitors and oral factor IIa (thrombin) - a new era for patients with an increased risk for thrombosis is emerging. However, the advantage of the new oral anticoagulants, which need no regular evaluation of the therapeutic range, could also be its disadvantage since regular pills for chronic use are prone for lack of adherence with a major impact on thrombo-embolic complications. This concern is based on the fact that lack of adherence is a common problem. Adherence rates are typically lower among patients with chronic conditions, as compared to those with acute conditions. Persistence among patients with chronic conditions is disappointingly low, dropping most dramatically after the first six months of therapy. Common causes for lack of adherence that are patient based, are forgetfulness and having other priorities. Reasons for conscious decisions to omit doses are mostly based on false interpretation of the benefits and risks (side-effects) of taking the medication, due to lack of information and emotional factors. Common health care barriers are poor access to as well as poor interaction with the professional. A review of the literature shows that most methods of improving adherence have involved combinations of education (information about the patient's condition and the treatment) to increase awareness and motivation, enhancement of self efficacy with structured and stepped behavioural interventions and empowerment by feedback, supervision or attention. To be more specific the methods that can be used to improve adherence can be grouped into four general categories: provide patient education; keep the intervention / dosing schedule as simple as possible; provide optimal increasing the hours when contact with a physician is possible; and improved communication between physicians and patients and educational interventions. Enhancing communication between the physician and the patient is a key and effective strategy in boosting the patient's ability to follow a medication regimen

Successful methods are complex and labour intensive when not using ICT solutions, thus innovative strategies that are practical for routine clinical use must be deployed. E-health support plays an increasing role in the treatment and dose advising of the current VKA treatment.

The above-mentioned relevant measures of increased adherence are all incorporated in a currently successfully implemented model for VKA treatment. In this approach patient education is supported by e-learning. With 16 hour a day 7 days a week on-line service the hours that a physician can be consulted are increased with a low threshold form of communication between physicians and patients,

Forgetfulness is contested by sending SMS and e-mail reminders.

Data from a regional Dutch healthcare insurance company on WIPPS in VKA patients showed a trend that there was less bleeding and thrombosis complications in this group of patients as compared to *usual care*- VKA patients (matched for age, gender, postal code etc.), suggesting improved compliance in the WIPPS group.

Study objective

NOACs have no need for regular monitoring, this could have an effect on adherence. It is our objective to study adherence and patient satisfaction in WIPPS guided and non-WIPPS guided patients using Rivaroxaban

Study design

This is a randomized controlled trial comparing one arm receiving usual care with the second arm receiving guided care by a Web Based Interactive Patient-Professional Support (WIPPS) system. The follow up durations will be one year.

Intervention

Every patient receives a satisfaction questionnaire at the beginning and the end of the study.

In addition, patients randomised to the WIPPS arm have to complete an e-learning on atrial fibrillation and anti-coagulation and the software used in the study, followed by an exam which they must pass before they can continue with the study. After passing the exam, the intake visit takes place where the satisfaction questionnaire is taken. Once entered in the study patients randomised to the WIPPS arm also have to report a status update every two weeks. The e-learning is repeated every six months.

Study burden and risks

With the arrival of new oral anticoagulants - i.e. oral factor Xa inhibitors and oral factor IIa (thrombin) - a new era for patients with an increased risk for thrombosis is emerging. However, the advantage of the new oral anticoagulants, which need no regular evaluation of the therapeutic range, could also be its disadvantage since regular pills for chronic use are prone for lack of adherence with a major impact on thrombo-embolic complications. Therefore, in the current study we investigate the potential beneficial effect of guided care WIPPS on the adherence in patients receiving Rivaroxaban AF, which is an indication for lifelong anticoagulation therapy.

The burden of this study is low. WIPPS guidance is non-invasive, and mainly consists of a brief online questionnaire which only takes a few minutes to complete once every two weeks. The benefit is a potential increase in adherence, which is likely to result in less thrombotic complications.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Age 18 and above
- Patients diagnosed with atrial fibrillation who have a CHADS₂-score of 2 or higher, or CHADS₂-VASc-score of 1 or higher
- Patients must be able to communicate with the nurse or physician through the web-based system.
- Patients must have a medical indication as endorsed by the treating medical specialist to switch to or start with Rivaroxaban

Exclusion criteria

- Younger than 18 years of age
- Not fluent in Dutch
- Pregnancy
- Life expectancy less than one year
- Reduced cognitive capacity
- Most recent creatinin clearance (24 hour creatinin clearance) less than 30 ml/min
- NYHA class III or IV heart failure

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	600
Type:	Anticipated

Ethics review

Not approved	
Date:	12-11-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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

CCMO

ID

NL44196.018.13