ICAD: Clinical validation study of a new algorithm for oral anticoagualant dosing.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26250

Source
Nationaal Trial Register

Brief title
ICAD

Health condition

Anticoagulant treatment.

Sponsors and support

Primary sponsor: Netherlands Thrombosis Foundation
Stichting Bazis
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Percentage of time therapeutic range, proportion of visits in shich the algorithm gave a proposal and the proportion that was accepted by the physician.

Secondary outcome

1. Mean time between visits;

2. Bleeding events;

3. Thrombotic events.

Study description

Background summary

Introduction:

Oral anticoagulants are among the most widely used drugs and have a sizable risk of severe bleeding complications. Efforts to improve dosing quality in oral anticoagulant control include the use of computer algorithms. Since the current algorithms are simplistic and give dosage proposals in a small fraction of patients, we developed an algorithm based on principles of system and control engineering that gives proposals in nearly all patients.

Objective:

To evaluate the new algorithm in clinical practice.

Design, Setting and Participants:

This is adouble-blind randomized controlled trial among patients with an indication for long-term anticoagulant treatment at the Leiden Anticoagulation Clinic. There are two interventions: oral anticoagulant dosing supported by the new algorithm (ICAD) or oral anticoagulant dosing by the standard algorithm (TRODIS).
Main outcome measures are the percentage of time in therapeutic range, proportion of visits in which the algorithm gave a proposal and the proportion of proposals that was accepted by the physicians.

Study objective

The equations used by most current algorithms are usually based on a simple pharmacodynamic model, which implies a linear function between the INR and the dosage. Our new algorithm consists of two sub models in which the first sub model describes the collective influence of all processes on the effect of the vitamin K antagonist and the second

sub model describes the relationship between the dosage and the corresponding INR. The second sub model includes a variable parameter to reflect the sensitivity of the patient that may change over time. Because of the inclusion of a parameter which relfects the sensitivity of the patient we think it is better capable of proposing a doasage wich leads to an INR within the therapeutic range.

Study design

N/A

Intervention

Oral anticoagulant dosage supported by the new algorithm (ICAD) and oral anticoagulant dosage supported by the algorithm TRODIS.

Contacts

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Eligibility criteria

Inclusion criteria

1. Indication for longterm anticoagulant therapy;

2. Age between 18 and 80.

Exclusion criteria

1. Paticipation in the patient selfmanagement program;

2. Staying long periods abroad;

3. Terminal stage of disease.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-08-2003
Enrollment:	712
Type:	Actual

Ethics review

Positive opinion

Date:	31-07-2006
Application type:	First submission

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
NTR-new	NL714
NTR-old	NTR724
Other	: P02-089
ISRCTN	ISRCTN27801917

Study results

Summary results

1. J Thromb Haemost. 2007 Aug;5(8):1644-9. Epub 2007 May 7.

2. Pasterkamp E, Kruithof CJ, Van der Meer FJ, Rosendaal FR, Vanderschoot JP. A model-based algorithm for the monitoring of long-term anticoagulation therapy. J Thromb Haemost. 2005;3:915-921.