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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26250

Bron
NTR

Verkorte titel
ICAD

Aandoening

Anticoagulant treatment.

Ondersteuning

Primaire sponsor: Netherlands Thrombosis Foundation
Stichting Bazis
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage of time therapeutic range, proportion of visits in shich the algorithm gave a

proposal and the proportion that was accepted by the physician.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Indication for longterm anticoagulant therapy;

2. Age between 18 and 80.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Paticipation in the patient selfmanagement program;

2. Staying long periods abroad;

3. Terminal stage of disease.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	14-08-2003
Aantal proefpersonen:	712
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	31-07-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL714
NTR-old	NTR724
Ander register	: P02-089
ISRCTN	ISRCTN27801917

Resultaten

Samenvatting resultaten

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.