The prediction of bleeding in in-hosptial patients using anticoagulants.

Het voorspellen van bloedingen bij patienten met antistollingsmedicatie in het ziekenhuis.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21983

Source
Nationaal Trial Register

Health condition

Eng: bleeding complications while using coumarins (vitamin K antagonist)
keywords: bleeding - coumarin - vitamin K antagonist - prediction model - risk factor
Dutch: Bloedingscomplicaites bij gebruik van coumarines (vitamine K antagonisten)
bloeding - coumarine - vitamine K antagonist - voorspelmodel - risico factor

Sponsors and support

Primary sponsor: Erasmus MC, Rotterdam
Source(s) of monetary or material Support: Erasmus MC, MRace - Doelmatigheid 2009

Intervention

Outcome measures

Primary outcome

INR > 4.5.

Secondary outcome

One of the following prescriptions:

1. Vitamin K prescription;

2. PCC prescription;

3. Tranexamic acid prescription;

4. Blood transfusion (platelets, plasma, erythrocytes).
Or death.

Study description

Background summary

Reduction of (avoidable) errors is one of the key goals of the patient safety program within Dutch healthcare in general and within the Erasmus MC in specific. This pilot project for identifying patients with a high risk of bleeding complications while using coumarins fits this goal.
Using electronic patient data, risk factors for a high risk of bleeding complications will be identified and a clinical prediction model for potential bleeding complications will be developed. This prediction model can be used on hospitalized patients using coumarins. A high INR (international normalized ratio), and/or use of the coumarin antidotes vitamin K and prothrombin complex concentrate (PCC), use of tranexamic acid, blood transfusions and death serve as indicators to identify these patients.
The objective is the identification of electronically available risk factors and the development of a clinical prediction model to identify patients at risk for a bleeding complication while using coumarins.

It is a (nested) case control study in hospitalized patients with one or more prescriptions of coumarins, in the four year period 2006-2009. This study will be carried out using (historically) documented electronic patient data. All patient data are coded using non-traceable codes.
Patients with an INR > 4.5 are generally regarded as being at high risk for a bleeding complication. Regression analysis will be used for data-analysis, using 'backward selection' to select the strongest predictors for having a high INR in a multivariate regression model.

Study objective

By developing a model which predicts the risk of bleeding with coumarin use, patients can be treated more effectively, potentially avoiding the need for specific antidotes. Besides decreasing the risk of bleeding (potentially resulting in less morbidity and mortality), such a prediction model may also lead to a reduction in healthcare costs.

Study design

Adult patients admitted in 2006-2009 will be included in this study.

Intervention

It is a nested case control study. Identification of risk factors for bleeding complications in patients using coumarins. With these risk factors a clinical prediction model for high risk of bleeding in patients using coumarins will be developed.

Contacts

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Eligibility criteria

Inclusion criteria

Hospitalized patients => 18 yr with an prescription for a coumarin within the 4-year period 2006-2009.

Exclusion criteria

N/A

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2010
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-12-2010
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	NL2551
NTR-old	NTR2669
Other	METC Erasmus MC, Rotterdam the Netherlands : 2010-287
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A