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

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

Gepubliceerd: 31-12-2010 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21983

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC, Rotterdam
Overige ondersteuning: Erasmus MC, MRace - Doelmatigheid 2009

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

INR > 4.5.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

's Gravendijkwal 230
A.D. Lindemans
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7033202

Wetenschappelijk

's Gravendijkwal 230
A.D. Lindemans
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7033202

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

N/A

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2010
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

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

Resultaten

Samenvatting resultaten
N/A