Prothrombin complex concentrate (Cofact ®) as a potential antidote for novel anticoagulants Dabigatran and Rivaroxaban.

Gepubliceerd: 06-04-2010 Laatst bijgewerkt: 18-08-2022

Based on its general pro-hemostatic potential, prothrombin complex concentrate may be effective in (completely or partially) reversing the anticoagulant effect of the new antithrombotic agents Dabigatran and Rivaroxaban.

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

Samenvatting

ID

NL-OMON22423

Bron
Nationaal Trial Register

Aandoening

Anticoagulants.
Antidote for bleeding.

Ondersteuning

Primaire sponsor: Prof. dr. M.M. Levi, Academic Medical Centre of Amsterdam
Overige ondersteuning: Cofact ® will be supplied by Sanquin

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is activation and inhibition of coagulation, as reflected by coagulation tests.

Toelichting onderzoek

Achtergrond van het onderzoek

An investigator initiated double blind cross-over study of the activation and inhibition of coagulation in healthy males who receive either Cofact or placebo after the administration of a novel anticoagulant. The two novel anticoagulants given are Dabigatran and Rivaroxaban. Blood samples will be collected at set times to assess coagulation assays.

Doel van het onderzoek

Based on its general pro-hemostatic potential, prothrombin complex concentrate may be effective in (completely or partially) reversing the anticoagulant effect of the new antithrombotic agents Dabigatran and Rivaroxaban.

Onderzoeksopzet

Subjects will start their oral medication at day -2. They will be admitted to the study ward on day 0. An i.v. catheter will be placed to withdraw blood samples. Blood samples are collected at the following times:

T= day -2 (before starting the oral anticoagulants), T= 0 (before the administration of Cofact/ Saline), and after the administration of Cofact/Saline at T= 15 min, 30 min, 60 min, 120 min, 240 min, 360 min and at 24 hrs.

The following assays will be performed: aPTT, PT, thrombin time (TT), Ecarin-clotting time (ECT), endogenous thrombin potential (ETP), prothrombin activation fragment F1+2, thrombin-antithrombin complex, thrombelastography, anti-factor Xa (in case of rivaroxaban), anti-factor IIa (in case of dabigatran).

Onderzoeksproduct en/of interventie

Subjects will be divided into two groups. Subjects in group 1 will take Dabigatran 2dd 150 mg on day -2, -1 and 0. Subjects in group 2 will take Rivaroxaban 2dd 20 mg on day -2, -1 and 0. After the fifth dose (on day 0) subjects will be randomized to receive Cofact ® (50 U/kg) or a similar volume of Saline as a single bolus dose i.v. over 15 minutes. After a 10 day wash-out period the procedure is repeated but the alternative treatment (Saline of Co-fact) is administered.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy males between 18-50 year;

2. No medical history of thrombotic disease or bleeding disorders;

3. Normal physical examination and laboratory screen;

4. Negative HIV-1, hepatitis B and hepatitis C serology.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History of allergic reaction to blood products;

2. Current participation in any other investigational drug study or within the past 30 days.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2010
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-04-2010
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	NL2149
NTR-old	NTR2272
Ander register	AMC 2009-219 : MEC 09/206
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A