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

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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**
NTR

**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