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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22423

Source
Nationaal Trial Register

Health condition

Anticoagulants.
Antidote for bleeding.

Sponsors and support

Primary sponsor: Prof. dr. M.M. Levi, Academic Medical Centre of Amsterdam
Source(s) of monetary or material Support: Cofact ® will be supplied by Sanquin

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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.

Study design

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).

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. History of allergic reaction to blood products;

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

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2010
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

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

Study results

Summary results
N/A