Low dose vitamin K to improve therapeutic quality control of oral anticoagulant treatment: a randomized double-blind placebo controlled trial.

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1. Oral anticoagulant control is less stable at a low average intake of vitamin K; 2. As a consequence, a low dose vitamin K supplement results in a more stable anticoagulant effect in patients using vitamin K antagonists (VKA); 3. Dietary intake...

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

Samenvatting

ID

NL-OMON25820

Bron
NTR

Verkorte titel
N/A

Ondersteuning

Primaire sponsor: Trombosestichting Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Quality of anticoagulant treatment;
2. Expressed as time in therapeutic range.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

It has been shown that oral anticoagulant control is less stable at a low dietary intake of vitamin K.

We hypothesize that a low dose vitamin K supplement results in a more stable anticoagulation in patients using vitamin K antagonists.

The primary objective of this study:

is to test this hypothesis clinically.

Methods:

The study is a double blind, randomized, placebo controlled trial in patients who use phenprocoumon and have an indication for long-term oral anticoagulant treatment.

Two hundred patients will be randomized to receive adjusted-dose phenprocoumon and a daily vitamin K supplement of 100 micrograms or to receive adjusted-dose phenprocoumon and placebo for 24 weeks.

The primary endpoint is the percentage of time the INR is within the therapeutic range.

Doel van het onderzoek

1. Oral anticoagulant control is less stable at a low average intake of vitamin K;

2. As a consequence, a low dose vitamin K supplement results in a more stable anticoagulant effect in patients using vitamin K antagonists (VKA);

3. Dietary intake of vitamin K is associated with sensitivity to VKA and stability of anticoagulant treatment;

4. Polymorphisms of the VKORC1 gene are associated with sensitivity to VKA and stability of anticoagulant treatment.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

1. Treatment group: 100 microgram vitamin K for 24 weeks;

2. Placebo group: placebo for 24 weeks.

Contactpersonen

Publiek

Leiden University Medical Center (LUMC),
Department of Hematology,
P.O. Box 9600
Eva Rombouts
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5264798

Wetenschappelijk

Leiden University Medical Center (LUMC),
Department of Hematology,
P.O. Box 9600
Eva Rombouts
Albinusdreef 2
Leiden 2300 RC
The Netherlands
+31 (0)71 5264798

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients treated at the Leiden anticoagulation clinic with an indication for long-term oral anticoagulant therapy using the vitamin K antagonist phenprocoumon;

2. Age between 18 and 80 years;

3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Treatment by a medical specialist for liver failure;

2. Haemo- or peritoneal dialysis;

3. Pregnancy or a planned pregnancy, puerperium;

4. Any chronic condition with an expected median survival of less than 6 months
an expectedinterruption of oral anticoagulant treatment of more than 1 week;

5. Self-management of oral anticoagulant therapy;

6. Other drugs affecting hemostasis (aspirin, heparin, clopidogrel).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland Status:	Werving gestopt
(Verwachte) startdatum:	16-11-2004
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
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	NL276
NTR-old	NTR314
Ander register	: project 2005.2
ISRCTN	ISRCTN14473912

Resultaten

Samenvatting resultaten
J Thromb Haemost. 2007 Oct;5(10):2043-8. Epub 2007 Jul 31.