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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25820

Source
Nationaal Trial Register

Brief title
N/A

Sponsors and support

Primary sponsor: Trombosestichting Nederland

Intervention

Outcome measures

Primary outcome

1. Quality of anticoagulant treatment;

2. Expressed as time in therapeutic range.

Secondary outcome

1. Number of INRs in therapeutic range;

2. Bleeding and thromboembolic complications.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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

2. Placebo group: placebo for 24 weeks.

Contacts

Public
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
Scientific
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

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-11-2004
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	09-09-2005
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	NL276
NTR-old	NTR314
Other	: project 2005.2
ISRCTN	ISRCTN14473912

Study results

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