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

Submission date	Recruitment status	Prospectively registered
20/12/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
20/12/2005	Completed	Results
Last Edited	Condition category	Individual participant data
15/08/2008	Haematological Disorders	Record updated in last yea

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

#### Secondary identifying numbers

Project 2005.2; NTR314

# Study information

#### Scientific Title

#### **Study objectives**

- 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

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval received from the local medical ethics committee

#### Study design

Randomised, double-blinded, placebo controlled parallel group trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Thrombosis, emboly, anticoagulant treatment

#### **Interventions**

- 1. Treatment group: 100 microgram vitamin K for 24 weeks
- 2. Placebo group: placebo for 24 weeks

#### **Intervention Type**

Supplement

#### **Phase**

**Not Specified** 

## Drug/device/biological/vaccine name(s)

Vitamin K

#### Primary outcome measure

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

#### Secondary outcome measures

- 1. Number of international normalised ratios (INRs) in therapeutic range
- 2. Bleeding and thromboembolic complications

#### Overall study start date

16/11/2004

#### Completion date

01/06/2006

# **Eligibility**

#### Key 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

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Upper age limit

80 Years

#### Sex

Both

## Target number of participants

200

## Key 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 expected interruption of oral anticoagulant treatment of more than 1 week
- 5. Self-management of oral anticoagulant therapy
- 6. Other drugs affecting haemostasis (aspirin, heparin, clopidogrel)

#### Date of first enrolment

16/11/2004

#### Date of final enrolment

01/06/2006

# Locations

#### Countries of recruitment

Netherlands

# Study participating centre Leiden University Medical Center

Leiden Netherlands 2300 RC

# Sponsor information

#### Organisation

Leiden University Medical Center (LUMC) (The Netherlands)

#### Sponsor details

Department of Hematology P.O. Box 9600 Leiden Netherlands 2300 RC

#### Sponsor type

Charity

#### Website

http://www.lumc.nl/english/start\_english.html

#### **ROR**

https://ror.org/05xvt9f17

# Funder(s)

# Funder type

Charity

#### Funder Name

Dutch Thrombosis Foundation (Trombosestichting Nederland) (The Netherlands)

# **Results and Publications**

## Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration