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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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