

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
Registration date 20/12/2005	Overall study status Completed	☐ Protocol
Last Edited 15/08/2008	Condition category Haematological Disorders	☐ Statistical analysis plan
		☐ Results
		☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised, double-blinded, placebo controlled parallel group trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

All

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)

ROR
<https://ror.org/05xvt9f17>

Funder(s)

Funder type
Charity

Funder Name
Dutch Thrombosis Foundation (Trombosestichting Nederland) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration