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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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
15/08/2008

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] 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

Study design
Randomised, double-blinded, placebo controlled parallel group trial

Primary study design
Interventional

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