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A study to assess whether complications of anti-coagulation treatment with vitamin K antagonists will diminish by supplementation of vitamin K

Submission date 17/03/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/03/2008	**Overall study status** Completed	
Last Edited 02/09/2008	**Condition category** Haematological Disorders	

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
P07.243

Study information

Scientific Title

Acronym
VIKS-2B

Study objectives
The bleeding complications of treatment with vitamin K antagonists will be less in number and severity when supplementation with vitamin K is given.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Medical Ethics Committee of Leiden University Medical Center on the 4th March 2008.

Study design
Randomised double-blind placebo-controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Anti-coagulation treatment

Interventions
The participants will be randomly allocated to the following two groups in equal numbers:
Treatment group: vitamin K, 1 capsule a day (1 dd) in the dose found in VIKS-2A (see http://www.controlled-trials.com/ISRCTN37109430: A study to find the optimal dose for vitamin K supplementation in patients being treated with vitamin K antagonists to create an anti-

coagulation effect)
Control group: placebo 1 dd

The duration of the intervention is flexible; this depends on the rate of recruitment. We aim to achieve the target number of recruitment in one year, and then the treatment will continue for two years. Therefore, in this case, the first and last participants will receive the intervention for three and two years, respectively.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin K supplementation

Primary outcome measure
1. Number of (bleeding) complications
2. Severity of (bleeding) complications

Duration of follow-up: start of intervention to two years after the end of recruitment period.

Secondary outcome measures
How do polymorphisms of the enzymes vitamin K epoxide reductase complex subunit 1 (VKORC1) and cytochrome P450 2C9 (CYP2C9) influence the effect of vitamin K supplementation?

Duration of follow-up: start of intervention to two years after the end of recruitment period.

Overall study start date
01/04/2009

Completion date
31/03/2012

Eligibility

Key inclusion criteria
1. Starting treatment with vitamin K antagonists less then four weeks before inclusion
2. Treatment with vitamin K antagonists for a minimal period of six months, with the therapeutic range of International normalised ratio (INR) between 2.5 and 3.5
3. Age between 18 and 85 years, either sex
4. Measurement of the INR by the Thrombosis Service Leiden
5. Informed consent

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
2200 patients

Key exclusion criteria
1. Treatment for liver failure
2. Dialysis, both peritoneal and haemodialysys
3. Pregnancy, or wish to get pregnant; lactational period
4. Known to have a chronic condition with a life expectancy of less than six months
5. An expected interruption of treatment with oral anti-coagulants for one week or longer
6. Participation in the self-management protocol

Date of first enrolment
01/04/2009

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Netherlands Heart Foundation (Nederlandse Hartstichting) (The Netherlands)

Sponsor details

P.O. Box 300
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Sponsor type
Charity

Website
http://www.hartstichting.nl

ROR
https://ror.org/05nxhgm70

Funder(s)

Funder type
Charity

Funder Name
Netherlands Heart Foundation (Nederlandse Hartstichting) (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