

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 31/03/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/09/2008	Condition category Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

Completion date

31/03/2012

Eligibility**Key inclusion criteria**

1. Starting treatment with vitamin K antagonists less than 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

85 years

Sex

All

Key exclusion criteria

1. Treatment for liver failure
2. Dialysis, both peritoneal and haemodialysis
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)

ROR

<https://ror.org/05nxhgm70>

Funder(s)

Funder type

Charity

Funder Name

Netherlands Heart Foundation (Nederlandse Hartstichting) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration