ISRCTN37109430 https://doi.org/10.1186/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

| | | |
|---|---|---|
| **Submission date**<br>17/03/2008 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>31/03/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>23/10/2020 | **Condition category**<br>Haematological Disorders | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr FJM van der Meer

**Contact details**
Leiden University Medical Center
Department of Thrombosis and Heamostasis
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 526 3901
f.j.m.van_der_meer@lumc.nl

## Additional identifiers

**Protocol serial number**
P07.243

## Study information

## Scientific Title
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

## Acronym
VIKS-2A

## Study objectives
The anti-coagulation treatment with vitamin K antagonists will be more stable and safer with the supplementation of a low daily dose of vitamin K.

## 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-coagulant treatment

## Interventions
The participants will be randomly allocated to the following four groups in equal numbers:
Group 1: 100 µg vitamin K1 (oral), 1 capsule per day (1 dd)
Group 2: 150 µg vitamin K1 (oral), 1 dd
Group 3: 200 µg vitamin K1 (oral), 1 dd
Control group: placebo (oral), 1 dd

The duration of the treatment is flexible, as is the inclusion period. Follow-up will take place six months after the closure of the inclusion period. This means the first patients will receive vitamin K or placebo for six months and the time the inclusion will take. The last patients will only receive vitamin K or placebo for six months.

## Intervention Type
Supplement

## Phase
Not Specified

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

### Primary outcome(s)
Quality of anti-coagulant treatment expressed as time in therapeutic range. Duration of follow-up: until six months after the closure of the inclusion period.

### Key secondary outcome(s))
Number of INRs in therapeutic range. Duration of follow-up: until six months after the closure of the inclusion period.

### Completion date
31/03/2009

## Eligibility

### Key inclusion criteria
1. Start 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 anf 3.5
3. Aged 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

### Total final enrolment
400

### 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**
01/04/2008

**Date of final enrolment**
31/03/2009

# 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

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/04/2011 | 23/10/2020 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |