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

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

#### Secondary identifying numbers

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

# 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-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 measure

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.

#### Secondary outcome measures

Number of INRs in therapeutic range. Duration of follow-up: until six months after the closure of the inclusion period.

#### Overall study start date

01/04/2008

#### 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

#### Age group

Adult

#### Lower age limit

18 Years

#### Upper age limit

85 Years

#### Sex

Both

#### Target number of participants

400 patients

#### 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)

#### Sponsor details

P.O. Box 300

The Hague

Netherlands 2501 CH +31 (0)70 315 5555 info@hartstichting.nl

## 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

# **Study outputs**

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