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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
17/03/2008

Recruitment status
No longer recruiting

Registration date
31/03/2008

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Haematological Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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