Gerandomiseerde vergelijkende studie naar verschillen tussen de biologische beschikbaarheid en de effectiviteit van vitamine K drank en vitamine K tabletten.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26078

Source
NTR

Brief title
N/A

Health condition

Anticoagulants.
Vitamin K antagonists.
Vitamin K

Coumarines.
Vitamine K antagonisten.
Vitamine K

Sponsors and support

Primary sponsor: Leiden University Medical Center, Department of Thrombosis and Hemostasis
Source(s) of monetary or material Support: Dutch Heart Foundation

Intervention

Outcome measures

Primary outcome

1. The difference between vitamin K levels in blood 4 hours after taking vitamin K tablets in comparison with vitamin K solution;

2. The difference in the number of INR-values lower than 2.0 when comparing vitamin K tablets with vitamin K solution in oil after 24 and 48 hours;

3. Difference in the decrease of INRs 24 hours after taking either vitamin K tablets or solution.
The difference in the number of INRs lower than 2.0 when comparing vitamin K tablets and solution after 24 and 48 hours.

Secondary outcome

1. The difference between area under the curve measured over 24 hours after taking vitamin K tablets in comparisson with vitamin K solution;

2. The difference in increase of the vitamin K levels in the blood 24 hours after taking either vitamin K tablets solution.

Study description

Background summary

Vitamin K solution was used for several years to antagonize the treatment with vitamin K antagonists. Vitamin K tablets came into the market as 'vitamin tablets' instead of medicines, but are easier to distribute and do have a longer shelf life. However, they are not shown to be as effective as the oral solution. We perform this study to investigate whether the bioavailability and effectiveness of the tablets and solution are comparable. Patients are therefore recruited from the anticoagulation clinic in Leiden, the Netherlands.

Study objective

The bioavailability and effectiveness of vitamin K tablets and solution are comparable.

Study design

Step 1: 0h;2h;4h;5h;6h;8h;10h; 24h

Step 2: 0h; 24h; 48h;

Step 3: 0h; 24h; 48h.

Intervention

Administration of vitamin K tablets or solution.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy subjects;

2. Patients being treated with phenprocoumon undergoing an invasive diagnostic or therapeutic procedure for which reducing of the INR is necessary;

3. Patients being treated with phenprocoumon having an INR above 7.0 for which reducing with vitamin K is necessary;

4. Age 18 years or older;

5. Informed consent.

Exclusion criteria

1. Being treated for liver failure;

2. Pregancy, pregnancy wish or lactational period;

3. Hemodialysis or peritoneal dialysis;

4. Participation in the self management program;

5. Inability to take care of own medication and/or proven non-compliance with treatment protocols.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-07-2011
Enrollment:	165
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-06-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3353
NTR-old	NTR3485
Other	METC LUMC : P10.177
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A