The effect of administering VITamin K preprocedural on the vitamin K dependent coagulation factors and the INR in patients anticoagulated with ACEnocoumarol (VITKACE-study)

Published: 29-08-2018
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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON46375

Source
ToetsingOnline

Brief title
VITKACE

Condition

- Other condition

Synonym
invasive procedure, oral anticoagulation

Health condition

stollingsfysiologie

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisvoorzieningen Gelderse Vallei
Source(s) of monetary or material Support: onderzoekssubsidie vanuit Ziekenhuis Gelderse Vallei

Intervention

Keyword: antagonize, INR, vitamin K, vitamin K antagonist

Outcome measures

Primary outcome

Plasma concentrations of prothrombin and factor VII at the day of the invasive

procedure.

Secondary outcome

- The number of patients with an INR <1.8 just prior to the invasive procedure.

- Number of thromboembolic or bleeding events occurring within 30 days after

the intervention.

- Time to achieve therapeutic INR in acenocoumarol users who are administered a

single dose of vitamin K 36-48 hours before the invasive procedure.

- Pharmacogenetic variation between the patients that reach an adequate INR and

those that don't.

Study description

Background summary

Patients using vitamin K antagonists (VKAs) need to have the anticoagulant effect reversed prior to invasive procedures in order to prevent bleeding complications to occur. At Gelderse Vallei Hospital (ZGV), these patients are

administered 10 mg of vitamin K 36-48 hours prior to the invasive procedure. Currently, there is no insight what factors cause this strategy to be successful.

Study objective

The primary objective is to identify which coagulation factors are associated with unsuccessful reversal of VKA activity. Secondary objectives include the assessment of the number of patients reaching normalized INR (i.e. <1.8) and the number of patients experiencing either thromboembolic or bleeding complications; pharmacogenetics of GGCX.

Study design

Observational study with additional blood draws.

Study burden and risks

Patients do not benefit individually from participating in this study. The burden of this study encompasses four additional blood draws and is therefore associated with negligible risk of injury.

Contacts

Public
Ziekenhuisvoorzieningen Gelderse Vallei

Willy Brandtlaan 10
Ede 6716 RP
NL
Scientific
Ziekenhuisvoorzieningen Gelderse Vallei

Willy Brandtlaan 10
Ede 6716 RP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients on acenocoumarol requiring an invasive procedure

Exclusion criteria

- Age < 18 years.
- Patients requiring periprocedural bridging therapy according to our local protocol based on national guidelines with low-molecular-weight-heparin (LMWH).
- Inherited or acquired coagulopathies.
- Inability or incompetency to give informed consent.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-09-2019

Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	vitamin K
Generic name:	vitamin K
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	29-08-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-08-2018
Application type:	First submission
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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
EudraCT	EUCTR2018-002291-41-NL

Register	ID
CCMO	NL63929.081.18