SWitching Acenocoumarol to Phenprocoumon for improved anticoagulation control during point-of-care INR monitoring (SWAP-trial)

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22099

Source
NTR

Brief title
SWAP

Health condition

anticoagulation
Vitamin K antagonists
Point-of-care
Time in therapeutic range

Sponsors and support

Primary sponsor: Erasmus University Medical Center
Source(s) of monetary or material Support: Stichting Trombosedienst & Artsenlaboratorium Rijnmond (STAR)

Intervention

Outcome measures

Primary outcome

Percentage of time in therapeutic range at study end

Secondary outcome

1. INR testing frequency

2. Percentage of measurements in therapeutic range

3. Percentage of INR followed by a significant dose adjustments, defined as any dose adjustment of 10% or more

4. Percentage INR variation

5. Difference in treatment satisfaction score (0-100), based on the visual analogue scale at study end

Study description

Study objective

Prior studies have shown reagent dependent differences in sensitivity to circulating clotting factor VII (FVII). This reagent dependent sensitivity to FVII can explain the INR differences between laboratory methods and point-of care devices found in earlier studies. Since FVII fluctuation and consequent INR variation is significantly lower in patients treated with the long-acting phenprocoumon compared to the short-acting acenocoumarol, switching patients from acenocoumarol to phenprocoumon may improve anticoagulant control during point-of-care INR monitoring

Study design

baseline and study end (7 months after study start)

Intervention

We will perform a single-center, prospective, open-label, randomized clinical trial, to determine if switching from acenocoumarol to phenprocoumon can improve time in therapeutic range during POC INR monitoring by a specialized anticoagulation clinic.

After informed consent, patients will be allocated to either switch to phenprocoumon or to

continue their treatment with acenocoumarol. After a transition period of 1 month, patients will be followed up for 6 months and TTR and secondary end points will be assesse

Contacts

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Eligibility criteria

Inclusion criteria

1.Provision of informed consent prior to any study specific procedures.

2.Patients with an indication for anticoagulant treatment with vitamin K antagonists who are treated with acenocoumarol.

3. Patients aged 18 years or above.

4. The patient has a target INR of 3.0 (therapeutic range 2.0-3.5) or 3.5 (therapeutic range 2.5-4.0)

5. The patient has an expected treatment duration of 6 months or longer from the moment of study entry

6. The patient is expected to have at least 3 months of treatment with VKA’s before study entry

Exclusion criteria

1. Patients who self-monitor their INR.

2. Patients who are treated with VKA other than acenocoumarol.

3. The patients’ life expectancy is less than 6 months.

4. Pregnant women, women who are breast feeding, and women of childbearing potential who are not intending to practice an adequate method of contraception during their participation in the study.

5. Patients with a scheduled chirurgical procedure during the study period

Study design

Design

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

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-09-2015
Enrollment:	880
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

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	NL5023
NTR-old	NTR5169
Other	EUDRACT : 2015-001757-33

Study results