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

Gepubliceerd: 16-04-2015 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22099

Bron
Nationaal Trial Register

Verkorte titel
SWAP

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus University Medical Center
Overige ondersteuning: Stichting Trombosedienst & Artsenlaboratorium Rijnmond (STAR)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage of time in therapeutic range at study end

Toelichting onderzoek

Doel van het onderzoek

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

Onderzoeksopzet

baseline and study end (7 months after study start)

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Erasmus MC - kamer NC-816 - Wytemaweg 80

J.S. Biederman
Postbus 5201, 3008 AE Rotterdam

Rotterdam 3015 CN
The Netherlands
030 733 73 45

Wetenschappelijk

Erasmus MC - kamer NC-816 - Wytemaweg 80

J.S. Biederman
Postbus 5201, 3008 AE Rotterdam

Rotterdam 3015 CN
The Netherlands
030 733 73 45

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	880
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5023
NTR-old	NTR5169
Ander register	EUDRACT : 2015-001757-33

Resultaten