Comparitive study of the stability of oral anticoagulant therapy using phenprocoumon or warfarin.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23351

Bron
NTR

Verkorte titel
N/A

Ondersteuning

Primaire sponsor: Leiden University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Time spent within therapeutic range, time to the first INR in range, percentage of INRs above range after initiation scheme, reaction of INR to interruption of coumarin or vitamin K administration.

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction:

Worldwide there are different coumarins available for oral anticoagulant treatment.

Warfarin, acenocoumarol and phenprocoumon are the coumarins most used and they differ mainly in their halflife.

A comparison between acenocoumarol and warfarin showed that warfarin was superior to the shortacting acenocoumarol. Another comparison between acenocoumarol and the long-acting phenprocoumon concluded that phenprocoumon should be prefered over acenocoumarol.

Methods:

We set up a randomised controlled trial in which an oral anticoagulant treatment with warfarin is compared to a treatment with phenprocoumon.

Patients are recruted at three different hospitals in the Netherlands at the departments of Cardiology, Internal Medicin or Orthopaedics.

Patients between 18 and 85 years with an indication for the use of oral anticoagulants for at least 3 months are invited to participate.

Inclusion started in March 2004 and is ongoing. Treatment is coordinated at the Leiden Anticoagulation Clinic. Patients are followed untill end of treatment or, for patients with an indication for prolonged treatment, during their first six months.

Endpoints:

Primary endpoints are the time spent in therapeutic range calculated according to the method of Rosendaal, the time untill an INR in the therapeutic range is reached after starting the treatment and the reaction of the INR to interruption of coumarin or vitamin K administration.

Doel van het onderzoek

Longacting coumarin derivatives can reach a more stable anticoagulant effect. Shortacting coumarins are more easy to adjust. The halflife of warfarin lies between the halflife of

acenocoumarol and phenprocoumon and can thereby possibly have the advantage of longacting coumarins as well as the advantage of shortacting coumarins.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Treatment group: oral anticoagulant treatment with warfarin.

Control group: oral anticoagulant treatment with phenprocoumon.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. No current use of anticoagulants;

2. Aged 18–85;

3. Indication for the use of oral anticoagulants;

4. Living in the workingarea of the Leiden Anticoagulation Clinic;

5. Adequate intelligence, informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;

2. Chemotherapy;

3. Hemo- of peritoneal dialysis;

4. Plasmafereses;

5. Contra-indication for the use of oral anticoagulants.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2004
Aantal proefpersonen:	500
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
Soort:	Eerste indiening

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	NL281
NTR-old	NTR319
Ander register	: P99-134
ISRCTN	ISRCTN60446748

Resultaten

Samenvatting resultaten
N/A