Het VISTA onderzoek:
Het VTE-predictiemodel als leidraad voor de duur van antistollingstherapie binnen de huidige richtlijnen voor patiënten met een veneuze-tromboembolie.

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Formalization of the current guidelines on VTE treatment duration with VKA, by means of using a VTE recurrence prediction model in patients with venous thrombo-embolism, will optimize its cost-effectiveness compared to care-as-usual. Only patients...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25558

Bron
NTR

Verkorte titel
VISTA

Aandoening

(Recurrent) Venous thromboembolism; Deep vein thrombosis; Pulmonary Embolism;(recidief) veneuze trombo-embolie; diep veneuze trombose; longembolie; VKA treatment duration; recurrent VTE prediction model

Ondersteuning

Primaire sponsor: Utrecht University/ Utrecht University Medical Center
Overige ondersteuning: ZonMW, the Netherlands Organisation for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Recurrent VTE during 24 months of follow-up after the initial 6 months of VKA treatment. VTE is defined as proximal DVT and/or fatal or non-fatal PE as confirmed by compression US for DVT and by (spiral CT) angiography and/or ventilation-perfusion lung scanning for PE.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Treatment of venous thrombo-embolism (VTE)- both deep venous thrombosis (DVT) and pulmonary embolism (PE)- with vitamin K antagonists (VKA) is highly effective in reducing morbidity and mortality. However, after standard VKA discontinuation after 6 months there is considerable risk of VTE recurrence, about 9 % after one year and 30% after 5 years. Long term treatment with VKA reduces risk of VTE recurrence to 1% a year, but at a cost of 2% increase in risk of major bleedings. There is limited evidence (and ongoing discussion) about the optimal treatment duration of VKA, given the challenge to obtain reduction in recurrent VTE thereby sustaining acceptable (low) risk of bleeding. Recently, a prediction model has been developed that accurately predicts the risk of VTE recurrence in patients with a first episode of unprovoked VTE. This strategy could give caregivers a more objective tool to tailor optimal duration and increase cost-effectiveness of VKA therapy in patients with VTE.

Objective:

To quantify the cost-effectiveness and safety of formal applying the guideline evaluating the risk-benefit ratio and the duration of anti-coagulant therapy by a previously developed VTE recurrence prediction model in patients with a first episode of unprovoked VTE as compared to care-as-usual.

Study design:

A single-centre, pragmatic randomized trial in patients with a documented first episode of unprovoked DVT or PE with a follow-up of 24 months.

Study population:

All adult patients, referred to their local Thrombosis Service Centre care for routine anti-coagulant treatment because of a confirmed first VTE.

Intervention:

Prediction model guided treatment (in high-risk patients, the initial, standard 6 months VKA treatment is continued for the entire follow-up period of 24 months whereas in low-risk patients long-term treatment is stopped after the standard initial period of 6 months) compared to care-as-usual.

Main study parameters/endpoints:

Primary outcome: Occurrence of major bleedings within 24 months of follow-up.

Secondary outcomes:

1. Occurrence of major bleedings;

2. Quality of life;

3. Cost-effectiveness.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

At baseline, several patient characteristics will be asked to all patients. Patients randomized to the index group may undergo a maximum of 3 venipuncture for D-dimer testing during the treatment phase of the study. For comparison reasons, patients randomized to the control group also undergo a venipuncture for D-dimer testing at the end of treatment with VKA. Furthermore, all patients will visit their local Thrombosis Service at 12 and 24 months during the follow-up phase in which Quality of Life' questionnaires will be asked and data for cost-effectiveness analyses.

Doel van het onderzoek

Formalization of the current guidelines on VTE treatment duration with VKA, by means of using a VTE recurrence prediction model in patients with venous thrombo-embolism, will optimize its cost-effectiveness compared to care-as-usual. Only patients with high-risk of VTE recurrence will receive indefinite treatment in absence of a high bleeding risk. In low-risk

patients, the use of possible bleeding risk-enhancing anticoagulants can be minimized safely and confined to the fixed duration as stated in the current guidelines.

Onderzoeksopzet

Follow up:
1. 3 months;

2. 12 months;

3. 24 months.

Onderzoeksproduct en/of interventie

Formalization of guidelines on duration of treatment, based on outcome of VTE recurrence prediction model compared to care-as-usual (that is: duration by physician’s decision).

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. First unprovoked VTE;

2. Legal age (>18 years).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Treatment indication VKA of at least 1 year
ie. recurrent VTE; atrial fibrillation; prosthetic valve;

2. Recent surgery with general or spinal anaesthesia, lower limb fracture with casting or active malignancy;

3. Pregnancy or puerperium;

4. Not willing or able to give informed consent.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-08-2011
Aantal proefpersonen:	1500
Type:	Verwachte startdatum

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	NL2562
NTR-old	NTR2680
Ander register	ZonMW : 171002214
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A