Lokale stolseloplossende behandeling bij een trombosebeen.

Gepubliceerd: 07-07-2010 Laatst bijgewerkt: 13-12-2022

Ultrasound-accelerated catheter-directed thrombolysis can reduce the posttrombotic syndrome incidence, improve quality of life and reduce medical costs in patients with acute primary iliofemoral deep vein thrombosis.

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

Samenvatting

ID

NL-OMON21278

Bron
NTR

Verkorte titel
CAVA-trial (CAtheter Versus Anticoagulation)

Aandoening

English key words: 'iliofemoral deep vein thrombosis'; 'posttrombotic syndrome'
Nederlandse kernwoorden: 'iliofemorale diep veneuze trombose'; 'posttrombotisch syndroom'

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre
Overige ondersteuning: ZonMw VEMI (Vroege Evaluatie Medische Innovatie)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1 year PTS incidence.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Iliofemoral deep venous thrombosis (IFDVT) is associated with significant postthrombotic morbidity. The presence of both obstruction and reflux significantly increases the chances for development of postthrombotic syndrome (PTS). Early thrombolysis may reduce the incidence of PTS as compared to treatment with conventional anticoagulant medication alone. Improvement of the health related quality of life (HRQOL) has been reported after surgical clot removal. The investigators hypothesize that such improvements could also be reached after catheter directed thrombolysis.

Objective:

To assess whether catheter-directed thrombolytic therapy for the treatment of IFDVT can safely and effectively reduce postthrombotic morbidity after one year. The secondary objective is to study whether catheter-directed thrombolytic intervention has a positive effect on the quality of life of patients with IFDVT and to assess late PTS.

Study design:

Prospective, single blinded, randomized, controlled, multicenter, intervention study.

Study population:

The study population includes all consecutive patients with IFDVT presenting at the emergency or outpatient departments of the participating centres. The thrombus should not be older than 14 days at randomization.

Intervention:

After randomization patients will be allocated to either conservative anticoagulant treatment alone or to catheter-directed thrombolysis combined with conservative anticoagulant treatment.

Main study parameters/endpoints:

The primary efficacy outcome is the incidence of PTS at one year; a decline in PTS incidence from 25% to 8% is anticipated. The secondary outcome is the Health related Quality of life and late PTS during follow-up. The principal safety outcome is major bleeding during anticoagulant therapy. Bleeding as well as events of recurrent thrombosis will be monitored. The patency of the venous system of the affected lower limb will be assessed as well as the percentage of clot lysis, after thrombolytic intervention. Additionally, measurements of markers of coagulation and inflammation will be performed during follow-up.

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

For patients who are randomized to the intervention arm of the study a hospital stay for 24-36 hour is mandatory during catheter directed thrombolysis. All patients will undergo additional imaging by MRA-vasovist and air phletysmography (APG) at baseline and after 12 months. Clinical follow-up visits will be matching usual care at 3, 6, 12 months; blood will be taken at these visits. Health-related quality of life (HRQOL) questionnaires will be filled out by all patients at baseline, 3, 6 and 12 months after the event; and once a year during the entire study duration. Further treatment will be in accordance with current guidelines for antithrombotic treatment. There may be an enhanced risk of bleeding in the thrombolysis group. The expected benefit is reduction of PTS from 25% to 8%, together with an improved quality of life.

Doel van het onderzoek

Ultrasound-accelerated catheter-directed thrombolysis can reduce the posttrombotic syndrome incidence, improve quality of life and reduce medical costs in patients with acute primary iliofemoral deep vein thrombosis.

Onderzoeksopzet

0, 3, 6 and 12 months follow-up.

Onderzoeksproduct en/of interventie

After randomization patients will be allocated to either conservative anticoagulant treatment alone or to catheter-directed thrombolysis combined with conservative anticoagulant treatment.

Contactpersonen

Publiek

PO Box 5800
Stephanie Bukkems
Maastricht UMC+, dept. Vascular surgery
Maastricht 6202 AZ
The Netherlands
+31 (0)6 53129126

Wetenschappelijk

PO Box 5800
Stephanie Bukkems
Maastricht UMC+, dept. Vascular surgery
Maastricht 6202 AZ
The Netherlands
+31 (0)6 53129126

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Objectively documented IFDVT;

2. Acute stage IFDVT, complaints less than 14 days;

3. Life expectancy longer than 6 months;

4. First thrombus in the affected limb.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History of GI bleeding within 1 year;

2. History of CVA/CNS disease;

3. Severe hypertension (>180/100 mmHg);

4. Active malignancy;

5. Surgery within 6 weeks;

6. Previous thrombosis of the affected limb (secondary thrombosis);

7. Chronic venous insufficiency;

8. Pregnancy;

9. ALAT > 3 times normal range;

10. eGFR < 30.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-05-2010
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-07-2010
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	NL2282
NTR-old	NTR2409
Ander register	Clinical trials.gov : NCT00970619
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A