Individually tailored elastic compression therapy after deep venous thrombosis (DVT).

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Tailoring elastic compression therapy to individual patients needs will not lead to an increased incidence of the post thrombotic syndrome, substantial costs will be saved and the quality of life of individual patients will improve.

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

Samenvatting

ID

NL-OMON20395

Bron
NTR

Verkorte titel
Acronym: The Ideal DVT study (Individualized duration of elastic compression therapy against long-term duration of therapy).

Aandoening

Problem studied: Post thrombotic syndrome. Preventive intervention: elastic compression stockings (ECS). Patients studied: patients after an acute event of DVT. Current practice is to prescribe ECS for 24 months after an event of acute DVT. It is currently not clear whether all patients benefit to the same extent from ECS therapy, or what the optimal duration for individual patients should be. Keywords: Elastic Compression Stockings, Deep Venous Thrombosis, Post Thrombotic Syndrome.

Ondersteuning

Primaire sponsor: MUMC+, Maastricht University Medical Center.
Overige ondersteuning: ZonMw (Dutch organization for medical research and innovation of healthcare)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The occurrence of PTS at 24 months after the event of acute DVT (the observers will be blinded to the allocated treatment arm).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

In the Netherlands, 25.000 patients each year are diagnosed with Deep Venous Thrombosis (DVT). Elastic compression stocking (ECS) therapy reduces the incidence of post thrombotic syndrome (PTS) following DVT from 50% without ECS to 20-30% after ECS therapy for two years. It is however unclear whether all patients benefit to the same extent from this therapy or what the optimal duration of ECS therapy for individual patients should be. ECS therapy is not only costly, inconvenient and demanding but sometimes also even debilitating. Substantial costs could be saved by tailoring therapy to individual needs and the quality of life for individual patients can be expected to improve.

Objective:

To assess the costs and effects of tailoring the duration of ECS therapy after DVT to individual patients needs.

Study design:

A multi-center, randomized, allocation concealed, single-blinded clinical trial in patients with acute proximal DVT with a follow-up of 24 months.

Study population:

Consecutive, adult outpatients after acute proximal DVT who present themselves at one of

the participating centers.

Intervention:

ECS therapy with a standard duration of 24 months versus tailored ECS therapy following an initial therapeutic period of 6 months, based on signs and symptoms according to a Villalta scale.

Main study parameters/endpoints:

Primary outcome: Percentage of patients with PTS at two year follow-up.

Secondary outcomes: 1. Health Related Quality of Life (HRQOL), 2. Recurrent venous thrombosis,3. Mortality due to venous thrombosis, 4. Costs and 5. Patient preference.

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

The study burden for patients is kept to a minimum and will comprise of regular visits and questionnaires. The study burden for clinicians is low. Patients will be seen at regular intervals (3, 6, 12 and 24 months) at the outpatient clinic. Patients will receive questionnaires preceding their visits. A clinical score to assess post thrombotic complaints will be performed at the out clinic visits. Based on our previous findings we expect that due to individual tailoring of therapy, 50% of patients will need ECS therapy for a period of maximum 12 months, instead of 24 months. HRQOL may be positively affected. Shorter therapy duration is not anticipated to have a negative implication on the incidence of PTS during the 24 months period of follow-up (pilot data; J Vasc Surg. 2010 Jul;52(1):132-8).

Doel van het onderzoek

Tailoring elastic compression therapy to individual patients needs will not lead to an increased incidence of the post thrombotic syndrome, substantial costs will be saved and the quality of life of individual patients will improve.

Onderzoeksopzet

1. Percentage PTS at 24 months (assessments performed at 3, 6, 12 and 24 months);

2. Data on HRQOL at baseline, 3, 6, 12 en 24 months;

3. Patient preference at 12 months.

Onderzoeksproduct en/of interventie

Elastic compression therapy with a standard duration of 24 months compared to individually tailored duration of elastic compression therapy, following an initial therapeutic period of 6 months, based on signs and symptoms according to the Villalta scale.

Contactpersonen

Publiek

P. Debyelaan 25
A.J. Cate-Hoek, ten
Internal Medicine, laboratory of Hematology
Maastricht 6262 AZ
The Netherlands
+31 (0)43 3871243

Wetenschappelijk

P. Debyelaan 25
A.J. Cate-Hoek, ten
Internal Medicine, laboratory of Hematology
Maastricht 6262 AZ
The Netherlands
+31 (0)43 3871243

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Legal age (18 yrs);

2. Informed consent;

3. Acute objectively documented DVT of the leg;

4. Adequate anticoagulation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous DVT in the affected leg;

2. Recurrent DVT in the first 6 months following inclusion;

3. Preexistent venous insufficiency (skin signs C4-C6 on CEAP score or requiring ECS therapy);

4. Contraindication for elastic compression therapy (arterial insufficiency);

5. Active thrombolysis;

6. Life expectancy < 6 months.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-03-2011
Aantal proefpersonen:	864
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-11-2010

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	NL2481
NTR-old	NTR2597
Ander register	ZonMw / METC MUMC : 171102007 / NL32073.068.10;

Resultaten

Samenvatting resultaten
1: Amin EE, Ten Cate-Hoek AJ, Bouman AC, Meijer K, Tick L, Middeldorp S, Mostard G, Ten Wolde M, van den Heiligenberg S, van Wissen S, van de Poel M, Villalta S, Serné E, Otten HM, Klappe E, Prandoni P, Prins MH, Ten Cate H, Joore MA. Individually shortened duration versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome: a cost-effectiveness analysis. Lancet Haematol. 2018 Nov;5(11):e512-e519. doi: 10.1016/S2352-3026(18)30151-0. Epub 2018 Oct 9. PubMed PMID: 30314712.

2: Amin EE, Bistervels IM, Meijer K, Tick LW, Middeldorp S, Mostard G, van de Poel M, Serné EH, Otten HM, Klappe EM, Joore MA, Ten Cate H, Ten Wolde M, Ten Cate-Hoek AJ. Reduced incidence of vein occlusion and postthrombotic syndrome after immediate compression for deep vein thrombosis. Blood. 2018 Nov 22;132(21):2298-2304. doi: 10.1182/blood-2018-03-836783. Epub 2018 Sep 20. PubMed PMID: 30237155.

3: Nagler M, Ten Cate H, Prins MH, Ten Cate-Hoek AJ. Risk factors for recurrence in deep vein thrombosis patients following a tailored anticoagulant treatment incorporating residual vein obstruction. Res Pract Thromb Haemost. 2018 Feb 3;2(2):299-309. doi: 10.1002/rth2.12079. eCollection 2018 Apr. PubMed PMID: 30046732; PubMed Central PMCID: PMC6055496.

4: Amin EE, Joore MA, Ten Cate H, Meijer K, Tick LW, Middeldorp S, Mostard GJM, Ten Wolde M, van den Heiligenberg SM, van Wissen S, van de Poel MHW, Villalta S, Serné EH, Otten HM, Klappe EH, Prandoni P, Ten Cate-Hoek AJ. Clinical and economic impact of compression in the acute phase of deep vein thrombosis. J Thromb Haemost. 2018 Jun 1. doi: 10.1111/jth.14163. [Epub ahead of print] PubMed PMID: 29856509.

5: Ten Cate-Hoek AJ, Amin EE, Bouman AC, Meijer K, Tick LW, Middeldorp S, Mostard GJM, Ten Wolde M, van den Heiligenberg SM, van Wissen S, van de Poel MH, Villalta S, Serné EH, Otten HM, Klappe EH, Bistervels IM, Lauw MN, Piersma-Wichers M, Prandoni P, Joore MA, Prins MH, Ten Cate H; IDEAL DVT investigators. Individualised versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome (IDEAL DVT): a multicentre, randomised, single-blind, allocation-concealed, non-inferiority trial. Lancet Haematol. 2018 Jan;5(1):e25-e33. doi: 10.1016/S2352-3026(17)30227-2. Epub 2017 Dec 5. PubMed PMID: 29217387.