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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20395

Source
NTR

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

Health condition

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.

Sponsors and support

Primary sponsor: MUMC+, Maastricht University Medical Center.
Source(s) of monetary or material Support: ZonMw (Dutch organization for medical research and innovation of healthcare)

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Health Related Quality of Life (HRQOL), will be measured by questionnaires SF-36, EuroQol-5D, Veines-Qol Dutch translated (time point baseline, 3, 6, 12 and 24 months);

2. Recurrent venous thrombosis (time point 24 months);

3. Mortality due to venous thrombosis (time point 24 months);

4. Costs will include direct costs (e.g. medical therapy) and indirect costs (e.g. travel) and will be measured by case record forms, hospital data and 5 retrospective cost-questionnaires (time point 3, 6, 12, 24 months);

5. Patient Preference will be elicited by conducting a discrete choice experiment (DCE) at time point 12 months.

Study description

Background summary

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).

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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

Eligibility criteria

Inclusion criteria

1. Legal age (18 yrs);

2. Informed consent;

3. Acute objectively documented DVT of the leg;

4. Adequate anticoagulation.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2011
Enrollment:	864
Type:	Actual

Ethics review

Positive opinion

Date:	09-11-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2481
NTR-old	NTR2597
Other	ZonMw / METC MUMC : 171102007 / NL32073.068.10;

Study results

Summary results

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.