Individually tailored elastic compression therapy after deep venous thrombosis in relation to the incidence of post thrombotic syndrome, a randomized multicenter trial

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To assess the costs and effects of tailoring the duration of elastic compression stocking (ECS) therapy after deep vein thrombosis (DVT) to individual patients needs.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON38265

Source
ToetsingOnline

Brief title
ideal DVT study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Embolism and thrombosis

Synonym
post phlebetic syndrome

Research involving

Human

Sponsors and support

Primary sponsor: interne geneeskunde laboratorium hematologie
Source(s) of monetary or material Support: Er iseen aanvraag ingediend bij zonmw doelmatigheid.

Intervention

Keyword: Deep vein thrombosis, Elastic compression therapy, individual tailoring therapy, Post thrombotic syndrome

Outcome measures

Primary outcome

Percentage of patients with Post Thrombotic Syndrome (PTS) at two year

follow-up.

Secondary outcome

1. Health Related Quality of Life, 2.Costs, 3.Recurrent venous thrombosis, 4.

Mortality due to venous thrombosis and 5. Patient preference.

Economic evaluation: Cost-effectiveness analysis from a societal perspective

for the extrapolation of the trial results a Markov Model will be used.

Study description

Background summary

The evidence sustaining the value of Elastic compression stocking (ECS) therapy following acute deep venous thrombosis (DVT) is derived from 2 randomized clinical trials. Incidences of PTS were observed to be reduced significantly (approximately 50%) by application of ECS therapy with a duration of 24 months in all patients. However, based on these studies it is still not clear whether all patients benefit to the same extent from ECS 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. Only one study so far assessed whether prolonged duration of ECS therapy was

superior to 6 months of ECS therapy following an event of proximal DVT. In this study no significant difference in the incidence of post thrombotic syndrome (PTS) was found. Our study will provide the lacking information on the individual benefit to patients and the optimal duration of ECS therapy. Alongside the clinical trial, a cost-effectiveness analysis from a societal perspective will elucidate the cost-effectiveness of this approach. In the Netherlands, 25.000 patients each year are diagnosed with Deep Venous Thrombosis (DVT). Substantial costs could be saved by tailoring therapy to individual needs and as a result the quality of life for individual patients can be expected to improve.

Study objective

To assess the costs and effects of tailoring the duration of elastic compression stocking (ECS) therapy after deep vein thrombosis (DVT) to individual patients needs.

Study design

a multi-center, randomized, allocation concealed, single-blinded clinical trial in patients with proximal deep venous thrombosis (DVT) with a follow-up of 24 months.

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.

Study burden and risks

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, in press).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All adult, consenting, consecutive outpatients with acute objectively documented proximal DVT of the leg
•All patients should be treated with a minimum of 5 days of Low Molecular Weight Heparins (LMWH) followed by oral anticoagulants with a target international normalized ratio (INR) of 2-3

Exclusion criteria

Previous DVT in the affected leg
•Recurrent DVT in the 6 months following inclusion
•Pre-existent venous insufficiency (skin signs C3-C6 on CEAP score or requiring ECS therapy)

•Contraindication for elastic compression therapy (e.g. arterial insufficiency)
•Active thrombolysis
•Life expectancy < 6 months

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2011
Enrollment:	864
Type:	Actual

Ethics review

Approved WMO

Date:	07-07-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	01-02-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	25-03-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-04-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-05-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-06-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-10-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-11-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-03-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

	Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-11-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL32073.068.10