Prospective study to the Optimal duration of Compression Therapy As prevention of chronic Venous Insufficiency After deep venous thrombosis

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ACT reduces the incidence of PTS after DVT. In the Dutch CBO-guidelines current therapy is adviced for 2 years after diagnosis because most PTS develops within 2 years after DVT, with a peak incidence in the first year.Some clinicians claim that one...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin vascular abnormalities
Study type	Interventional

Summary

ID

NL-OMON35400

Source
ToetsingOnline

Brief title
OCTAVIA-study

Condition

- Skin vascular abnormalities
- Embolism and thrombosis

Synonym
post-thrombotic syndrome; chronic complaints of the leg after deep vein thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Fonds NutsOhra;Stichting Voorzorg;Stichting Medicina et Scientia

Intervention

Keyword: chronic venous insufficiency, deep vein thrombosis, elastic stockings, post-thrombotic syndrome

Outcome measures

Primary outcome

Primary outcome:

- The incidence of PTS in the second post-thrombotic year after one versus two

years of ambulant compression therapy

Secondary outcome

Secundary outcomes:

- Can venous ultrasound discriminate between patients after one year ACT in

risk of developing PTS

- Can baseline characteristics be used as prognostic markers for developing PTS

- What influence does (the absense of) ACT and PTS has on quality of life

Study description

Background summary

In the past years much research is done to diagnostic and therapeutic aspects of deep vein thrombosis (DVT) and one of its major complications, the post-thrombotic syndrome (PTS). The clinical presentation of PTS can vary from mild oedema with little complaints to severe swelling of the leg with chronic pain and in the worst case even ulceration. Above that, PTS has a negative influence on quality of life and has social economic consequences for patient and the health care system. Ambulant compression therapy (ACT) has proven to

significantly decrease the incidence of PTS. Few research has been done to te optimal duration of ACT or factors that help predict this.

Study objective

ACT reduces the incidence of PTS after DVT. In the Dutch CBO-guidelines current therapy is adviced for 2 years after diagnosis because most PTS develops within 2 years after DVT, with a peak incidence in the first year.
Some clinicians claim that one year ACT may be evenly effective, but there's no scientific evidence yet to confirm that. Also patient characteristics may influence the risk of developing PTS, such as age, gender, BMI, thrombus location or venous insufficiency.
Main objective of the study is to evaluate optimal duration of ACT after DVT and to assess risk factors for PTS.

Study design

The study is designed as prospective, single blind, randomised, multicenter trial. All patients aged 18y and older with ultrasound proven proximal DVT of the leg are eligible for inclusion. One year after diagnosis subjects are randomised into two groups: 1) continuing ACT for another year; 2) no ACT in second year post-DVT. For secondary outcomes echo duplex and laboratory samples are taken at baseline. Also quality-of-life assessment and compliance is measured for all study subjects. Follow up is set to 15 months: twice telephone interview and two visits to the outpatient clinic.

Intervention

Two groups:
1) continuing ACT for another year; 2) no ACT in second year post-DVT.

Study burden and risks

Burden:
- 20cc of blood is drawn (once)
- once duplex ultrasound of the leg
- phone interview at T=3 en T=15 months
- three times outpatient clinic at T=0, 6 and 12 months

Risks:
- hardly any risks

(see protocol for more information (in Dutch))

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 patients with one year adequate therapy after echo duplex proven proximal DVT of the leg
informed consent

Exclusion criteria

recurrent ipsilateral DVT (known riskfactor of PTS)
PTS developped in first year post-thrombosis
DVT only distal of popliteal vein
contra-indication for (stopping) compression therapy as indicated by treating physician
no informed consent

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2009
Enrollment:	516
Type:	Actual

Medical products/devices used

Generic name:	elastic stockings
Registration:	No

Ethics review

Approved WMO Date:	19-01-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-03-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-04-2009

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-05-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-06-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-01-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-03-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-06-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-09-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL25244.100.08
Other	NTR1442, Ned.Trialregister