Optimal duration of Compression Therapy As prevention of chronic Venous Insufficiency After deep venous thrombosis

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21019

Source
NTR

Brief title
OCTAVIA

Health condition

post-thrombotic syndrome (posttrombotisch syndroom), compression therapy (compressietherapie), elastic stockings (elastische kousen), venous insufficiency (veneuze insufficientie), deep venous thrombosis (diep veneuze trombose)

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht, department of Internal Medicine
Source(s) of monetary or material Support: Fonds NutsOhra (http://www.fondsnutsohra.nl)

Intervention

Outcome measures

Primary outcome

- The incidence of post-thrombotic syndrome in the second year of compression therapy.

Secondary outcome

- Evaluation of duplex ultrasound after one year compression therapy as predictive marker for PTS.

- Evaluation of baseline characteristics as predictive markers for PTS.

- Evaluation of quality of life (QoL)

Study description

Background summary

Prospective single-blind study to the optimal duration of ambulant compression therapy (ACT) after deep venous thrombosis as prevention of the post-thrombotic syndrome. After one year of ACT patients are randomized to either continuing ACT for a following year or stopping therapy. At inclusion, a blind duplex ultrasound is performed to evaluate its predictive value in PTS, as well as evaluation of baseline characteristics and laboratory findings. Quality of Life assessment is done at inclusion and after one year follow-up.

Study objective

We hypothesise that one year compression therapy after DVT is equally effective as two years in the prevention of the post-thrombotic syndrome - in selected patients.

Study design

T=0 randomization, duplex ultrasound, QoL

T=3 follow-up PTS (phone interview)

T=6 follow-up PTS (outpatient clinic)

T=12 follow-up PTS (outpatient clinic), QoL

Intervention

At inclusion, patients will be randomized in two groups; one receiving a following year of compression therapy, one without.

Contacts

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Eligibility criteria

Inclusion criteria

1. All patients with deep venous thrombosis who received one year of compression therapy.

Exclusion criteria

1. Recurrent ipsilateral DVT

2. Contra indication for (stopping) compression therapy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	460
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL1381
NTR-old	NTR1442
Other	: 0801-60 Fonds NutsOhra
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A