

# Elastic stockings after varicose vein surgery: useful or nonsense.

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Our hypothesis is that routine application of elastic stockings after varicose vein surgery is not beneficial with regard to pain- and physical functioning scores, complications, edema formation, time before returning to work and analgesics...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON20732

### Bron

Nationaal Trial Register

### Verkorte titel

ESaVS

### Aandoening

The standard surgical treatment for varicose veins is stripping of the greater saphenous vein. More recently minimally invasive techniques like endovenous laser therapy of the incompetent greater saphenous vein have gained increasing popularity. Post-operatively after both techniques, patients usually receive compression therapy with elastic stockings. However, no evidence is available to support this routine and frequently the patients experience discomfort from the use of these stockings.

## Ondersteuning

### Primaire sponsor: Hulsewé

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## Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

The primary endpoint of the study is the pain score. Pain will be measured using a visual analogue scale. In the first week patients will keep score of their pain daily and in the following 5 weeks they will register their pain scores weekly. We will investigate the difference between the group with and the group without elastic stockings in these parameters.

## Toelichting onderzoek

### Achtergrond van het onderzoek

The standard surgical treatment for varicose veins is stripping of the greater saphenous vein. More recently minimally invasive techniques like endovenous laser therapy of the incompetent greater saphenous vein have gained increasing popularity. Post-operatively after both techniques, patients usually receive compression therapy with elastic stockings. However, no evidence is available to support this routine and frequently the patients experience discomfort from the use of these stockings. Our hypothesis is that routine application of elastic stockings after varicose vein surgery is not beneficial with regard to pain- and physical functioning scores, complications, edema formation, time before returning to work and analgesics consumption.

The main objective is to determine whether the post-operative application of elastic stockings after varicose vein surgery is useful to reduce post-operative pain. Secondly we want to determine whether there is a difference in physical functioning scores, complications, leg

edema, time before returning to work and analgesics consumption between wearing and not wearing elastic stockings post-operatively.

Patients can choose either surgical treatment or endovenous treatment. Then patients will be randomised to either a group who wears elastic stockings 2 weeks post-operatively or a group who does not wear elastic stockings post-operatively after the procedure.

The study population consists of patients from 18 to 65 years, both male and female, who are diagnosed with primary stem varicose veins and who will be treated with inverted stripping of the greater saphenous vein with high ligation of the saphenofemoral junction or endovenous laser therapy.

One group wears elastic stockings (class II) for two weeks post-operatively and one group does not wear elastic stockings.

The main study endpoint are the pain scores. Secondly we will assess the number of complications, functioning scores, number of re-interventions, amount of analgesics consumption, time before returning to work and leg edema.

## **Doel van het onderzoek**

Our hypothesis is that routine application of elastic stockings after varicose vein surgery is not beneficial with regard to pain- and physical functioning scores, complications, edema formation, time before returning to work and analgesics consumption.

## **Onderzoeksopzet**

1. Pain: VAS-score in a diary: Pre-operatively, each day in the first week postoperatively, followed by a VAS-score at the end of each week up to week 6;
2. Complications: 2 days, 14 days and 6 weeks post-operatively;
3. Leg volume: pre-operatively, 2 days, 14 days and 6 weeks post-operatively;
4. Analgesics consumption in a diary. Each day for 6 weeks post-operatively;
5. Time before returning to work: on follow up at 14 days or 6 weeks;
6. RAND-36 and AVVQ: pre-operatively, 2 days, 14 days and 6 weeks post-operatively.

## **Onderzoeksproduct en/of interventie**

Patients will receive elastic stockings (class II) up to the thigh during the day for two weeks. Stockings with a pressure gradient are used for treatment of venous insufficiency. These stockings are usually given for 2 weeks post-operatively. The open-surgically treated patients will undergo is inverted stripping of the greater saphenous vein with high ligation of the saphenofemoral junction. The endovenously treated patients will undergo is endovenous

laser therapy (EVLT).

The investigational treatment is the absence of stockings in comparison to the use of stockings.

## Contactpersonen

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age between 18 and 65 years;
2. Duplex-proven varicose veins with insufficient saphenofemoral crosse;
3. CEAP-classification: C2-4EpAs,pPr;
4. Informed consent;
5. Suitable for surgical treatment and/or endovenous laser therapy.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;
2. Refusal of informed consent;
3. Deep venous thrombosis in medical history;
4. Previous surgery to vascular structures in lower extremities;
5. Secondary varicose veins;
6. Ulcerative lesions on lower extremities;
7. Contra-indication for use of elastic stockings.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2009
Aantal proefpersonen:	270
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies

Datum: 22-05-2009  
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	NL1718
NTR-old	NTR1828
Ander register	METC Atrium-Orbis-Zuyd : 09-T-03
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Resultaten

### Samenvatting resultaten

N/A