

VESPA Trial: Endovenous laser treatment versus crossectomy of the small saphenous vein.

Gepubliceerd: 24-11-2008 Laatste bijgewerkt: 13-12-2022

Endovenous laser treatment of the small saphenous vein is comparable to crossectomy with regard to recurrence and therapy failure.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20493

Bron

Nationaal Trial Register

Verkorte titel

N/A

Aandoening

insufficient small saphenous vein

Ondersteuning

Primaire sponsor: AngioCare BV

Overige ondersteuning: AngioCare BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Insufficiency after 6 weeks (therapyfailure)

- Insufficiency after 1 year (recurrence)

Toelichting onderzoek

Achtergrond van het onderzoek

Venous insufficiency has a high incidence worldwide. It is seen in 5-15% of all men en 15-30% of all women in western countries, varying from cosmetic complaints to chronic venous insufficiency and ulcers.

The prevalence of insufficiency of the small saphenous vein (SSV) is 10-18%. In the early twentieth century the surgical procedure of choice for insufficiency of the great saphenous vein (GSV) was the saphenofemoral ligation and GSV stripping.

Since stripping of the SSV resulted in a large number of nerve damages of the sural nerve, the method was adjusted to the saphenopopliteal ligation. The percentage of therapy failure (persistent insufficiency of the SSV perioperatively) is 25%. Reflux at one year was seen in 52%.

The number of therapy failure is explained by the variable anatomy of the SSV and its junction.

Endovenous laser treatment (EVLT) is a minimal invasive, percutaneous, endovenous technique causing heat mediated steam bubbles resulting in endothelial damage and occlusion of the venous segment. EVLT is a widely used technique for treatment of insufficiency of the GSV. The use of EVLT for treatment of the insufficient of the SSV has not been investigated earlier by a randomized trial.

Due to the fact that the SSV is cannulated under ultrasound guidance, it is certain the correct vein is being treated.

This may result in a reduction of therapy failures and long term insufficiency.

Doel van het onderzoek

Endovenous laser treatment op the small saphenous vein is comparable to crossectomy with regard to recurrence and therapy failure.

Onderzoeksopzet

Questionnaires preoperatively and at 1, 2, 6 and 12 weeks and 12 months.

Duplex at 6 weeks and 12 months.

Onderzoeksproduct en/of interventie

Endovenous laser treatment (EVLT)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Insufficiency of the small saphenous vein
CEAP 2 to 6
2. Age > 18 years old
3. Comprehension of the dutch language
4. Treatment of a least 10 cm

5. Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Diameter less than 2 mm
2. Simultaneous insufficiency of the large saphenous vein
3. Arterial insufficiency
4. Pregnancy
5. Recurrent insufficiency of the small saphenous vein
6. Spiral shape of the small saphenous vein

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-11-2008
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 24-11-2008
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	NL1484
NTR-old	NTR1554
Ander register	TWOR : 2008/11
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A