‘Comparison of costs and patient reported outcomes of endovenous techniques in the treatment of incompetent saphenous veins;’ A single center, double blinded, randomized controlled trial.

Gepubliceerd: 08-02-2010 Laatst bijgewerkt: 15-05-2024

N/A

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

Samenvatting

ID

NL-OMON22362

Bron
Nationaal Trial Register

Aandoening

varicose veins, endovenous treatment, VNUS, endolaser

Ondersteuning

Primaire sponsor: no sponsor
Overige ondersteuning: fund= initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Patient treatment satisfaction in terms of health related quality of life improvement;
2. (Post-operative) pain scores;
3. Clinical changes (venous clinical severity scores and CEAP-classification);
4. (Serious) side effects.

Toelichting onderzoek

Achtergrond van het onderzoek

Surgical ligation and stripping of the saphenous veins has shown extended recovery times, higher post-operative pain scores and inferior patient satisfaction. Side effects like pain, bruising and nerve damage have been reported frequently. Surgical treatment of the small saphenous veins is known of its high percentage of recurrences after treatment.

With the advantage of minimally invasive ultra-sound guided techniques new treatment opportunities have been created to combine an optimal occlusion rate of the incompetent vein with a minimum of side effects. As mentioned in the introduction endolaser- and radiofrequency ablation have both a good comparable effectiveness and surgery more often makes place for these endovenous techniques.

It depends on the specialist and available hospital devices which technique- the radiofrequency or the lasertherapy- is chosen for the treatment of the incompetent saphnenous veins. In the Netherlands radiofrequency and endolaser are becoming increasingly popular because of the reimbursement of health care costs in the Netherlands and the high effectiveness for these techniques.

To make firm recommendations there is a need for a well designed prospective trial in which comparison of costs and patient related outcomes between laser en radiofrequency are studied.

Data derived from such a study are indispensable for the development of guidelines on the treatment of varicose vein insufficiency aimed at maximizing patient acceptability and minimizing costs. This can contribute to a standardization and guideline for the treatment of varicose veins by endovenous ablation techniques.To compare effectiveness in terms of costs and patients preference between the VNUS fast closure procedure and the radial fiber 1470 nm endolaser. These are two equally accepted and applied treatments for treatment of patients with incompetent saphenous veins (both GSV en SSV).

Doel van het onderzoek

N/A

Onderzoeksopzet

Start including 01-04-2010.

Stop 01-04-2011.

Onderzoeksproduct en/of interventie

Treatment of saphenous incompetence with VNUSclosureFAST system, or with the radial fiber 1470 nm endolaser.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Primary truncal saphenous incompetence;

2. Normal deep venous system;

3. Reflux time > 0.5 s after distal compression in standing position (in GSV or SSV);

4. Patient should be physical able and willing to be treated with one of the two treatments;

5. Age > 18 years;

6. No sex discrimination;

7. Enough knowledge/understanding of the Dutch language;

8. Diameter > 4 mm due to the catheter used in both endovenous techniques.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Signs of DVT- residues visible on duplex;

2. Thrombus in vein of interest;

3. Previous GSV or SSV treatment;

4. Pregnancy;

5. Known malignancy;

6. Known adverse reaction for used local anaesthesia.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2010
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-02-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34867
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2085
NTR-old	NTR2202
CCMO	NL30280.068.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34867

Resultaten

Samenvatting resultaten
N/A