FOAM-study veins.

Gepubliceerd: 31-01-2006 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON26519

Bron
NTR

Verkorte titel
N/A

Aandoening

Primary varicose veins due to greater saphenous vein insufficiency

Ondersteuning

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cumulative probability of recurrent varicose vein at 18-24 months after treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Varicose veins in the legs is a common health problem. Ten percent of the population needs medical intervention. It causes high health care costs.Nowadays treatment modalities include surgery and duplex guided foam sclerothrapy. Both treatments are equally effective in terms of recurrences, however some studies indicate superiority of surgery and other studies indicating superiority of scelrotherapy. Costs associated with both treatments and patient preferences have never been studied. There is a need for a well-designed study comparing the effectiveness, the costs and patient acceptability and minimizing costs. The hypothesis underlying this study is that duplex guided foam sclerotherapy may be cost saving and is more acceptable for patients, because there is no need for anaesthesia and incisions and it is without side-effects, such as scars, haemotomas and a painful recovery period of at least 7 days. We designed a randomized controlled trial, the number of patients needed per group is estimated to be n=230. The primary outcome measure is the cumulative probability of recurrent varicose vein within 24 months after treatment. Secondary outcome measures are quality of life(as measured by EuroQol-5D), patient preferences(as measured by cojoint analysis) and costs. Cost-minimization analysis with potentially cost savings of 339.328 euros per year for the adherence(=target) population of the University Hospital of Maastricht. The study will take approximately 36 months in total.

Doel van het onderzoek

The hypothesis underlying this study is that duplex guided foam sclerotherapy may be cost saving and is more acceptable for patients than ligation and stripping of the greater saphenous vein, because there is no need for anaesthesia and incisions and it is lecking several side-effects, such as scars, haematomas and a painful recovery period of at least 7 days known after surgical intervention.

Onderzoeksproduct en/of interventie

1. Standardized duplex guided foam sclerotherapy;
2. Standardized surgery procedure.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Primary trunkal varicositas of the GSV;
2. Age > 18 years;
3. Reflux>0.5 s and insufficiency of the SF-junction measured by duplex;
4. Reflux for at least 20 cm of the GSV in the upper leg;
5. Informed consent;
6. Normal deep venous system.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Signs of DVT found with duplex;
2. Immobility;
3. Allergy for polidocanol in the past;
4. Life-expectation < 3 years;
5. Pregnancy;
6. Abnormal Deep Venous System;
7. Active ulcus cruris.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2006
Aantal proefpersonen:	460
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-01-2006
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	NL598
NTR-old	NTR654

Register	ID
Ander register	: N/A
ISRCTN	ISRCTN74375188

Resultaten

Samenvatting resultaten
N/A