Single Ambulatory Phlebectomy versus endovenous Thermal Ablation with concomitant ambulatory Phlebectomies

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To compare single ambulatory phlebectomies (SAP) with or without delayed endovenous thermal ablation (EVTA) (after 9 months) with combined thermal ablation and phlebectomies (TAP) (control arm).

Ethical review	Approved WMO
Status	Pending
Health condition type	Venous varices
Study type	Interventional

Summary

ID

NL-OMON42057

Source
ToetsingOnline

Brief title
SAPTAP study

Condition

- Venous varices

Synonym
saphenous vein, varicose veins

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Beroepsvereniging: Benelux vereniging voor de Flebologie

Intervention

Keyword: cost-effectiviness, endovenous thermal ablation, single ambulatory phlebectomies, varicose veins

Outcome measures

Primary outcome

Cost-effectiveness

Secondary outcome

Elimination of reflux in GSV (or AASV), patient reported outcomes (including

symptoms, satisfaction and health related quality of life), direct and indirect

costs, clinical class of the CEAP classification, venous clinical severity

score and predictors of success.

Study description

Background summary

It is suggested that reflux of the saphenous trunk may be reversible.
Therefore, treating varicose veins in a more conservative manner by SAP may be a cost effective strategy.

Study objective

To compare single ambulatory phlebectomies (SAP) with or without delayed endovenous thermal ablation (EVTA) (after 9 months) with combined thermal ablation and phlebectomies (TAP) (control arm).

Study design

Multicentre randomised controlled trial

Intervention

SAP (with or without delayed EVTA) or TAP with follow-up at 3, 9, 12, and 60 months

Study burden and risks

in approximately 25% of all treated patients with varicose veins and reflux of the GSV or AASV, ablation of the trunk can be avoided resulting in fewer complications and costs. However in 1/3 of these patients the SAP procedure will not be sufficient and patients will need a second intervention with EVTA.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients with primary incompetent GSV and tributaries and patients with primary incompetent AASV and tributaries.

Exclusion criteria

previous treatment of ipsilateral GSV trunk or tributary (or in case of AASV, previous treatment of ipsilateral AASV trunk or tributary) deep venous thrombosis and agenesis, post-thrombotic syndrome of the obstructive type, pregnancy and arterial disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	520
Type:	Anticipated

Ethics review

Approved WMO Date:	17-09-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-03-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	09-09-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24499
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL49701.078.14
OMON	NL-OMON24499