

Cryo strip versus classic strip of the great saphenous vein.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28805

Source

Nationaal Trial Register

Brief title

N/A

Health condition

Cryo strip
VSM
GSV
Klassieke strip
Venous
Venous surgery
Veneus
Classic strip
Great saphenous vein
Vene saphena magna

Sponsors and support

Primary sponsor: initiations : T.M.A.L. Klem / C.H.A. Wittens / R. Schutte
performers: T.M.A.L. Klem / M. Schnater / A. van Oers / C.H.A. Wittens / R. Schutte

Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

Recurrence, confirmed by venous duplex.

Secondary outcome

1. Operation time;
2. Neurological damage after surgery;
3. Quality of life.

Study description

Background summary

In this trial we compare cryo strip versus classic strip of the great saphenous vein. Primary outcome is recurrence rate, conformed by venous duplex.

Study objective

Recurrence rate of cryo strip is the same as classic strip of the great saphenous vein.

Study design

N/A

Intervention

Cryo strip of the great saphenous vein versus classic strip of the great saphnous vein.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with primary varicosis and incompetence of the great saphenous vein and saphenofemoral junction (confirmed by duplex). Only patients with C2, C3, C4 varicosis (CEAP-classification).

Exclusion criteria

1. C5, C6 varicosis;
2. Extreme adipositas (BMI>40);
3. Deep venous occlusion;
4. Incompetence of the small saphenous vein;
5. Aarterial occlusive disease of the legs;
6. Inability to understand the Dutch language;
7. Recurrence of varicosis of the leg.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2002
Enrollment:	520
Type:	Actual

Ethics review

Positive opinion	
Date:	10-03-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL902
NTR-old	NTR926
Other	:
ISRCTN	ISRCTN61851091

Study results

Summary results

N/A