Cryo strip versus classic strip of the great saphenous vein

Submission date	Recruitment status	Prospectively registered
11/04/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
11/04/2007	Completed	Results
Last Edited	Condition category	Individual participant data
22/09/2021	Surgery	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number NL902 (NTR926)

Study information

Scientific Title

Cryo strip versus classic strip of the great saphenous vein

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, active controlled, parallel group, multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Venous surgery

Interventions

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

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Recurrence, confirmed by venous duplex.

Key secondary outcome(s))

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

Completion date

01/10/2006

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

- 1. C5, C6 varicosis
- 2. Extreme adipositas (Body Mass Index [BMI] greater than 40)
- 3. Deep venous occlusion
- 4. Incompetence of the small saphenous vein
- 5. Arterial occlusive disease of the legs
- 6. Inability to understand the Dutch language
- 7. Recurrence of varicosis of the leg

Date of first enrolment

01/08/2002

Date of final enrolment

01/10/2006

Locations

Countries of recruitment

Netherlands

Study participating centre Berglustlaan 44a

Rotterdam Netherlands 3054 BJ

Sponsor information

Organisation

Saint Franciscus Hospital (Sint Franciscus Gasthuis [SFG]) (The Netherlands)

ROR

https://ror.org/007xmz366

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre (The Netherlands)

Funder Name

Albert Schweitzer Ziekenhuis (The Netherlands)

Funder Name

Sint Franciscus Gasthuis (SFG) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration