

Cryo strip versus classic strip of the great saphenous vein

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

No

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