

# Cryo strip versus classic strip of the great saphenous vein

<b>Submission date</b> 11/04/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/09/2021	<b>Condition category</b> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****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 measure**

Recurrence, confirmed by venous duplex.

**Secondary outcome measures**

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

**Overall study start date**

01/08/2002

**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

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

520

**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)

### Sponsor details

Kleiweg 500  
Rotterdam  
Netherlands  
3045 PM

### Sponsor type

Hospital/treatment centre

### Website

<http://www.sfg.nl/>

### 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

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration