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# To evaluate surgical treatments of great saphenous vein insufficiency: Endovenous LAser treatment versus Crossectomy and Stripping

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| **Submission date**<br>23/04/2011 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>19/05/2011 | **Overall study status**<br>Completed | |
| **Last Edited**<br>01/09/2015 | **Condition category**<br>Circulatory System | |

**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**
RELACS v1.7 (10.09.2004)

## Study information

**Scientific Title**
A prospective, Randomised, two-centre study to evaluate surgical treatments of great saphenous vein insufficiency: Endovenous LAser treatment versus Crossectomy and Stripping

## Acronym
RELACS

## Study objectives
Clinical recurrence is less frequent 2 years after endovenous laser treatment with a 11% difference compared with high ligation and stripping

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Medical Council of the Saarland (Ärztekammer des Saarlandes) Saarbrücken, Germany, 29/07/2004, identification-no. 98/2004

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Great saphenous vein insufficiency

## Interventions
Group A : Endovenous Laser Treatment (EVLT): EVLT of the great saphenous vein is performed with an 810 nm Diode laser (bare fibers) using Seldinger's technique ultrasound guided under tumescent local anaesthesia. The energy dose is intended to be 20 J/cm² delivering 20 W laser power. The additional phlebectomy of side branches is allowed.

Group B : High Ligation (Crossectomy) and Stripping (HLS): Standard surgical procedures are performed, consisting of transection of all groin tributaries, flush ligation of the saphenofemoral junction with non-resorbable sutures and neoreflux protection with a continuous stump suture, followed by invagination stripping of the great saphenous vein just below knee under tumescent local anaesthesia. The additional phlebectomy of side branches is allowed.

## Intervention Type
Procedure/Surgery

## Primary outcome(s)
Recurrent varices after surgery (REVAS) evaluated at 12 and 24 months follow up visit

## Key secondary outcome(s))
1. Duplex recurrence
2. Side effects
3. Homburg Varicose Vein Severity Score

4. Chronic Venous Insufficiency Questionnaire
5. Venous Refilling time (DPPG)
6. Patients' satisfaction is measured using visual analogue scale based questionnaires

Follow-up visits are scheduled in the first postoperative week (side effects), at 3 months [side effects, Homburg Varicose Vein Severity Score (HVVSS), Chronic Venous Insufficiency Questionnaire (CIVIQ), Venous refilling time (DPPG), patient's satisfaction], at 12 months [Duplex recurrence, HVVSS, CIVIQ, DPPG, patient's satisfaction] and at 24 months (Duplex recurrence, HVVSS, CIVIQ, DPPG, patient's satisfaction)

### Completion date
31/03/2007

# Eligibility

### Key inclusion criteria
1. Great saphenous vein (GSV) insufficiency with saphenofemoral incompetence and reflux at least down to the knee level
2. Chronic venous insufficiency and/or symptoms caused by GSV incompetence and/or severe clinical findings at risk of varicose vein bleeding, thrombophlebitis or deep vein thrombosis
3. Age 18 - 65 years (at randomisation)
4. Performance status according to American Society of Anesthesiology (ASA) I-II

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Previous surgical interventions in the groin area with the exception of inguinal herniotomy
2. Anterior or posterior accessory vein incompetence
3. Small saphenous vein insufficiency requiring treatment at the same limb
4. Acute deep venous thrombosis or postthrombotic syndrome
5. Known thrombophilia associated with a high risk of thromboembolism
6. Arterial occlusive disease > Fontaine IIA and/or ankle-brachial index below 0.8
7. Active malignancy (diagnosed during the past 5 years)
8. Poor compliance or missing ability to understand the study related procedures
9. Females pregnant or nursing

### Date of first enrolment

01/09/2004

**Date of final enrolment**
31/03/2007

# Locations

**Countries of recruitment**
Germany

**Study participating centre**
**The Saarland University Hospital**
Homburg
Germany
66421

# Sponsor information

**Organisation**
The Saarland University Hospital (Germany)

**ROR**
https://ror.org/01jdpyv68

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded (Germany)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/01/2012 | | Yes | No |
| Results article | results | 01/11/2015 | | Yes | No |