

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

Submission date 23/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/09/2015	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 (Ärzttekammer des Saarlandes) Saarbrücken, Germany, 29/07/2004, identification-no. 98/2004

Study design

Randomised controlled 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

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/09/2004

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400

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)

Sponsor details

Department of Dermatology, Venerology and Allergology

c/o Knuth Rass MD

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Homburg

Germany

66421

Sponsor type

Hospital/treatment centre

Website

<http://www.uniklinikum-saarland.de>

ROR

<https://ror.org/01jdpv68>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Germany)

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

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