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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/05/2011	**Overall study status** Completed	
Last Edited 01/09/2015	**Condition category** Circulatory System	

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
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

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
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Sponsor type
Hospital/treatment centre

Website
http://www.uniklinikum-saarland.de

ROR
https://ror.org/01jdpyv68

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