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Quality of life and benefit for patients: bipolar radiofrequency-induced thermotherapy (RFITT) versus crossectomy and stripping

Submission date 04/11/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 08/05/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/05/2015	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Varicose veins are swollen and enlarged veins that usually occur on the legs. They can be treated with surgery to remove the affected veins or with thermotherapy, in which the affected veins are burned and closed. At the moment there is not enough evidence regarding the benefits of the different treatments for varicose veins, especially for thermotherapy. The aim of our study is to find out whether thermotherapy provides better results compared with surgery.

Who can participate?
Patients aged 18 - 70 with varicose veins.

What does the study involve?
Participants will be randomly allocated to undergo either thermotherapy or surgery. The participants will be followed-up regularly for 5 years after the treatment.

What are the possible benefits and risks of participating?
By entering the study participants get the chance to try a new treatment for free.

Where is the study run from?
Krankenhaus Tabea (Germany).

When is the study starting and how long is it expected to run for?
From November 2014 to October 2019.

Who is funding the study?
Artemed SE (Germany).

Who is the main contact?
Dr Guido Bruning

Contact information

Type(s)
Scientific

Contact name
Dr Guido Bruning

Contact details
Krankenhaus Tabea GmbH & Co. KG
Kösterbergstr. 32
Hamburg
Germany
22587

Additional identifiers

Study information

Scientific Title
Quality of life and benefit for patients: bipolar radiofrequency-induced thermotherapy (RFITT) versus crossectomy and stripping: a prospective randomized multi-centre trial

Acronym
CelArt

Study objectives
Quality of life and benefit for the patient is higher 5 years after bipolar radio frequency induced thermotherapy (RFITT) compared with high ligation (crossectomy) and stripping.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Council of Hamburg (Ärztekammer Hamburg), Germany, approved 10/06/2014 (confirmed
amendments on 04/04/2014 and 13/05/2014), identification no. PV4495

Primary study design
Interventional

Study design
Randomized controlled prospective multi-centre trial

Study type(s)
Treatment

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

Interventions

Group A: ultrasound-guided bipolar radio frequency induced thermotherapy (RFITT) is performed under tumescent local anaesthesia. 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 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

Phase
Not Applicable

Primary outcome(s)
Quality of life, benefit for the patients and patients' satisfaction is measured using visual analogue scale (VAS) based questionnaires, pain scale according to VAS, Venous Clinical Severity Score (VCSS), Patient Benefit Index (PBI-v[prä] and PBI-v[post]) and Freiburger quality of life questionnaire for veins (FLAQvs) and open-ended questionnaire. Measured at preoperative visit and after 3 months, 1 year, 2 years, 3 years, 4 years and
5 years.

Key secondary outcome(s)
1. Minor and major complications
2. Recurrent varices after treatment (REVAT) evaluated at 3, 6, 12, 24, 36, 48 and 60 months follow-up visit

Completion date
09/10/2019

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
3. Diameter of GSV at measuring point 3 cm distal of the junction vena epigastrica superficialis (VES) maximal 15 mm in standing position
4. Performance status according to American Society of Anesthesiology (ASA) I-II
5. Surgical procedure in tumescent local anesthesia (TLA) or total intravenous anesthseia (TIVA) in combination with TLA
6. Written consent
7. Distance of place of residence to study centre <= 150 km
8. Age 18 - 70 years (at randomisation)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Incompetence of vena saphena parva (VSP) requiring treatment at the same limb, anterior accessory vein incompetence requiring treatment at the same limb
2. Previous sclerotherapy of VSM, previous endovenous treatment of VSM, previous surgical interventions in the groin area
3. Recurrences in the groin area
4. Permanent oral anticoagulation with e.g, Marcumar, Warfarin, Rivaroxaban
5. Acute thrombophlebitis, deep venous thrombosis or post-thrombotic syndrome (post-thrombotic syndrome), incompetence of deep veins (vena femoralis superficialis and vena poplitea)
6. Known thrombophilia associated with a high risk of thromboembolism
7. Arterial occlusive disease > Fontaine IIA
8. Polyneuropathia
9. Performance status according to American Society of Anesthesiology (ASA) III - VI
10. Active malignancy (diagnosed during the past 5 years)
11. Females pregnant or nursing
12. Distance of place of residence to study centre > 150 km
13. No written consent
14. Age <18 or >70 years (at randomisation)

Date of first enrolment
01/12/2014

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
Germany

Study participating centre
Krankenhaus Tabea GmbH & Co. KG
Hamburg
Germany
22587

Sponsor information

Organisation
Artemed SE (Germany)

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 expected to be made available