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Endovenous laser treatment of the great saphenous vein using a bare fibre versus tulip fibre

Submission date	Recruitment status	[ ] Prospectively registered
09/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/04/2010	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Marc Vuylsteke

Contact details
Sint-Andriesziekenhuis
Secr Heelkunde
Krommewalstraat 11
Tielt
Belgium
8700
+32 (0)51 425 060
marc.vuylsteke@me.com

Additional identifiers

Study information

Scientific Title
Randomised multicentre clinical trial: endovenous laser treatment of the great saphenous vein using a bare fibre versus tulip fibre

Acronym
Tulip Trial

Study objectives
Prospective comparative trial of endovenous laser treatment of the great saphenous vein using a bare fibre versus non-touch catheter attached at the fibre.

Varicose vein insufficiency is a very common pathology. Until recently the golden standard treatment for this superficial venous incompetence was to perform a crossectomy and a stripping of the saphenous vein. Unfortunately this radical treatment has some disadvantages like post-operative pain, haematomas in the stripping area, paresthesia and a high recurrence rate.

Endovenous laser treatment (ELT) has been introduced as a new mini-invasive alternative. The difference with the classic treatment is that the crossectomy is no longer performed and the saphenous vein is obliterated in a percutaneous way. The most common used lasers have a frequency of 810 - 940 - 980 nm and recently 1320 - 1500 nm. This treatment has a substantial lower morbidity, a shorter sick leave and less post-operative pain compared with a classical stripping. Nevertheless some inconveniences such as post-operative ecchymosis, bruising and periphlebitis jeopardise the recovery.

Some of these side-effects can be due to the direct contact between the fibre tip and the vessel wall. From a technical point of view ELT also has some imperfections: the bare fibre used for ELT is a rigid fibre. When this fibre is introduced in a saphenous vein, which usually has some small tortuosities and turnings, the fibre has always a tendency to stretch. As a consequence of this stretching, the fibre tip frequently hits the vessel wall. Examining the fibre location on per-operative ultrasound control, we can see the fibre tip most frequently situated in a very eccentric position in the vein, with the tip touching the vein wall.

Tumescent anaesthesia induces spasm of the vein around the fibre and can diminish this effect. But even then, especially in larger veins, the fibre tip stays in an eccentric position. When in such a situation the energy is delivered at the fibre tip, a direct contact between the fibre tip and the vessel wall results in a destruction and ulceration or perforation of the vein. A consequence of this is a very uneven application of light energy. When a specimen of vein, which has been treated with ELT, is examined histologically, a line of damaged vessel wall is seen with carbonised vein wall and ulcerations and perforations, while the rest of the vessel wall stays unaffected. These perforations cause the post-operative appearance of ecchymosis and can also injure the perivenous tissue, especially when the tumescent fluid is not correctly surrounding the vein. Other parts of the vein wall remain unaffected. This uneven energy application can be the cause of some of the imperfections of ELT, like post-operative ecchymosis, inflammation around the treated vein (periphlebitis) and pain.

Aim of the study:
In this prospective trial we like to evaluate the use of a new safety fibre tip. The tulip-shaped self-expandable distal end at the fibre tip expands intraluminally and pushes away the vein wall. The shape of the self expandable tip allows withdrawal from the fibre and catheter according to the usual procedure. The special shape however helps to prevent the fibre moving further into the vein, thus minimising the risk entering the deep venous system and will avoid possible damage, like perforation of the vein wall, while navigating into the veins.

Can the use of this safety fibre tip avoid some of the imperfections of ELT? In this trial two patient groups will be compared: one in which a normal bare fibre is used and a second one in

which the safety fibre tip is used. Primary outcome will be the occlusion rates at 1 month and 6 months post-operatively. Secondary outcomes will be the possible side-effects of these treatments: looking for the post-operative incapacity to work, the amount of used painkillers, the appearence of post-operative ecchymosis, periphlebitis and a post-operative quality of life-score.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Local commission for ethical approval in Tielt approved on the 14th October 2009 (ref: OG135; advice: CE 2009.09)
2. Ethics Committee of University Hospital Gasthuisberg approved on the 9th February 2010 (ref: B32220108042; S52072)

Primary study design
Interventional

Study design
Multicentre comparative randomised clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Varicose disease, endovenous laser treatment.

Interventions
Patients with an incompetent great saphenous vein will be treated with endolaser ablation. In this treatment a laser fibre is introduced intraluminal and the emitted light energy is absorbed by blood, water and/or the vein wall. The aim of this treatment is an irreversible obliteration of the treated saphenous vein. We like to compare the use of a non-touch catheter attached to the fibre with a normal bare fibre. This non-touch catheter is fixed at the distal end of the fibre and has some self-expandable blades at his distal end. When expanded these blades centres the fibre tip intraluminal and thus avoids the direct contact between the fibre tip and the vein wall.

Half of the patients will be treated with a normal bare fibre and the remnant with this new non-touch fibre (Tulip fibre).

Treatment is performed in a out-patient setting. Patients stay about 3 - 4 hours in the hospital, where a duplex venous-mapping is made. The endovenous laser treatment takes about 30 - 45 minutes. The follow-up duration is 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Occlusion rate of the treated veins at one month and six months post-operatively:
A duplex scan is scheduled at one month and six months. We use the Groupe d' Évaluation des Lasers et de l'Échographie Vasculaire (GELEV, part of the "Société Française d'Angéiologie") score to interpret the occlusion rate. This duplex score makes it possible to evaluate the morphological development of the treated veins. For this purpose we used the proximal measured diameter of the treated vein, which is located 2 cm distal to the saphenofemoral junction. This diameter was compared in the various outpatient reviews, and the veins were classified using the GELEV score. Morphological change after treatment:
Level 0: no occlusion, refluxing vein, unchanged vein
Level 1a: partial occlusion with proximal reflux
Level 1b: partial occlusion without reflux
Level 2a: complete occlusion with unchanged or larger diameter
Level 2b: complete occlusion with diameter reduction greater than 30%
Level 3: complete occlusion with diameter reduction greater than 50%
Level 4: fibrotic cord, vein not visible

Key secondary outcome(s)
Possible side-effects of the treatment:
1. Ecchymosis (measured 5 days post-operatively): we developed a scale in which the post-operative ecchymosis around the ablated vein is measured in square centimetres, and this measured surface is divided by the length of the treated vein.
2. Pain score: visual analogue scale (0 - 10) measured 5th post-operative day and one month post-operatively
3. Intake of analgetics: how many days? how many tablets?
4. Incapacity to work: expressed in days
5. Quality of life score: CIVIQ2 auto-questionaire. The construction and validation of a quality of life questionnaire (CIVIQ), originally designed to analyse changes in quality of life (QoL) caused by venous insufficiency, was used to analyse the two-week post-operative morbidity caused by the treatment. This 20-item questionnaire (CIVIQ2) provides a profile on four QoL dimensions (psychological, pain, physical and social) specific to venous derangement of the lower limb. The CIVIQ2 has been demonstrated to be a valid, reliable, stable and sensitive scale. The quality of life questionnaire had to be completed on the 14th post-operative day and to be returned at the one month post-operative control.
6. Patient satisfaction rate: visual analogue score (0 - 10)

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Patients with insufficiency of the great saphenous vein with functional and/or aesthetical inconvenience
2. 1470/1500 nm endovenous laser treatment
3. Aged between 18 - 80 years
4. Male or female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Key exclusion criteria
1. Deep venous insufficiency
2. Cross-dilatation with more than two incompetent side-branches
3. Maximal diameter of the saphenous vein greater than 15 mm
4. Therapeutical anticoagumlation or hypocoagulopathy
5. Hypercoagulopathy/thrombophilia
6. Peripheral arterial occlusive disease: Ankle-Brachial Index (ABI) less than 0.85 or history of claudication or ischaemia
7. Pregnancy
8. Patients younger than 18 years and older than 80 years
9. Bilateral treatment
10. Insufficiency of the small and/or anterior saphenous vein

Date of first enrolment
01/03/2010

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Belgium

Study participating centre
Sint-Andriesziekenhuis
Tielt
Belgium
8700

Sponsor information

Organisation
Sint-Andriesziekenhuis vzw (Belgium)

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Belgium)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes