# Tomy; lasercrossectomy versus EVLA

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24885

**Source**
NTR

**Brief title**
Tomy

**Health condition**

Recurrence
Varicose veins
EVLA
Lasercrossectomy

### Sponsors and support

**Primary sponsor:** Stichting Centrum Oosterwal
**Source(s) of monetary or material Support:** Biolitec Pharma
Otto Schotstrasse 15
07745 Jena
DE

### Intervention

### Outcome measures

**Primary outcome**

Primary Objective:

To prove that there is less development of recurrence and neoreflux, caused by AASV incompetence ,originating from the SFJ in the laser crossectomy group than in the traditionally treated EVLA group.

**Secondary outcome**

Secondary Objectives:

The Laser crossectomy procedure is safe with similar risk of thrombotic complications after both treatments.
There will be a difference in severity of venous disease and quality of life measurements in favour of laser crossectomy

# Study description

**Background summary**

For ten years ago High (Flush) Ligation and Stripping (HL/S) of the Great Saphenous Vein (GSV) was the standard treatment for GSV incompetence. During the procedure all tributaries entering the sapheno-femoral junction (SFJ) were ligated and/or resected, followed by stripping of the thigh portion of the GSV. Inadequate ligation of the sapheno-femoral Junction (SFJ) and these tributaries is suggested to be one of the causes of recurrent varicosities. However, current minimally invasive techniques that abolish axial vein reflux do not specifically interrupt these tributaries and critics of these techniques believe that this may compromise their durability. Duplex Ultrasound (DUS)-findings after HL/S revealed that besides inadequate ligation the majority of recurrence was secondary to neovascularisation at the SFJ. However on the other hand, endovenous procedures are associated with a risk for recanalization and neoreflux in persistent open junctional tributaries. Several RCT's comparing endovenous ablation with HL/S showing apparently more neoreflux in groin related tributaries, especially the anterior accessory saphenous vein (AASV) after endovenous ablation in comparison with HL/S. (3-6, 7) One of the reasons can be the positioning of the tip of the fibre/catheter not close enough to the SFJ. This will increase the risk leaving a residual stump with open tributaries that arises the possibility that they become incompetent by pressure through an incompetent terminal valve which cause neoreflux.(8) To diminish the prevalence of SFJ recurrence caused by incompetent accessory veins after endovenous ablation it could be wise to avoid a residual GSV stump formation if possible analogous to open surgery. In most cases, if present, the AASV joins the GSV closest to the SFJ to prevent neoreflux in the AASV.

Bare tip endovenous laser fibres and ClosureFAST RFA catheters both have a forward thrust of heat associated with the technique. That's why many authors advise to stay about 1,5- 2 cm of the confluence to prevent intimal damage at the SFJ which can provoke a heat induced thrombus (EHIT) or deep venous thrombosis (DVT). (9) It is assumed that with the use of a radial two ring laser fibre, without a forward laser beam, it is possible to occlude the

saphenous vein more close the SFJ in a safe way.(10) To prove that this occlusion leads to less varicose vein recurrence caused by axial neoreflux in AASV, we want to study patients in which a visible AASV is present before treatment. (50% of patients) (7, 11) It is also important to investigate what happens with the other tributaries in both groups and if occlusion will induce neovascularization.

ABR nr. 52367 Tomy study Investigator: JA Lawson

Sponsor: Biolitec versie 1.1 Coordinator: SA Gauw

Version number: 1.0; may 2015 8 of 43

Objective:

The aim of this randomized controlled study is to detect less clinical AASV recurrence with neoreflux at 1 and 2 years follow-up after Laser crossectomy in comparison with usual EVLA using a 1470 nm radial two rings fibre. (Biolitec)

### Study objective

The aim of this randomized controlled study is to find a difference in clinical AASV recurrence with neoreflux at 1 and 2 years follow-up after Laser crossectomy in comparison with usual EVLA using a 1470 nm radial two rings fibre. (Biolitec)

### Study design

4 x in 2 years

### Intervention

EVLA and lasercrossectomy

## Contacts

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# Eligibility criteria

## Inclusion criteria

1. Patients age > 18 < 80 years.

2. Patients who have an incompetent GSV with venous symptoms.

3. GSV suitable for EVLA

4. Mean diameter of the GSV > 3 mm.

5. DUS visible AASV joining the GSV

6. Incompetent SFJ after provocation manoeuvres

7. CEAP C2-C6

## Exclusion criteria

1. Patients age < 18 > 80 years.

2. Mean diameter of GSV < 0,3 cm

3. GSV not suitable for endovenous ablation

4. AASV not joining the GSV

5. The use of Warfarin or other oral coagulans

6. Risk factors for DVT

7. Competent SFJ.

8. CEAP < 2

9. Patients needing bilateral endovenous GSV treatment

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-01-2016 |
| Enrollment: | 100 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 04-06-2015 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL5283 |
| NTR-old | NTR5390 |
| Other | METC Alkmaar : 52367 |

# Study results