

**Erasmus MC**

Universitair Medisch Centrum Rotterdam



## **COLA trial**

Wendy S.J. Malskat

Erasmus MC Rotterdam, The Netherlands

CACVS, January 23rd 2016

# COLA trial, BJS 2015

Randomized clinical trial

## Randomized clinical trial of 940- *versus* 1470-nm endovenous laser ablation for great saphenous vein incompetence

W. S. J. Malskat, J. Giang, M. G. R. De Maeseneer, T. E. C. Nijsten and R. R. van den Bos

Department of Dermatology, Erasmus MC, Burgemeester s' Jacobplein 51, 3015 CA Rotterdam, The Netherlands

Paper accepted 17 September 2015

Published online in Wiley Online Library ([www.bjs.co.uk](http://www.bjs.co.uk)). DOI: 10.1002/bjs.10035

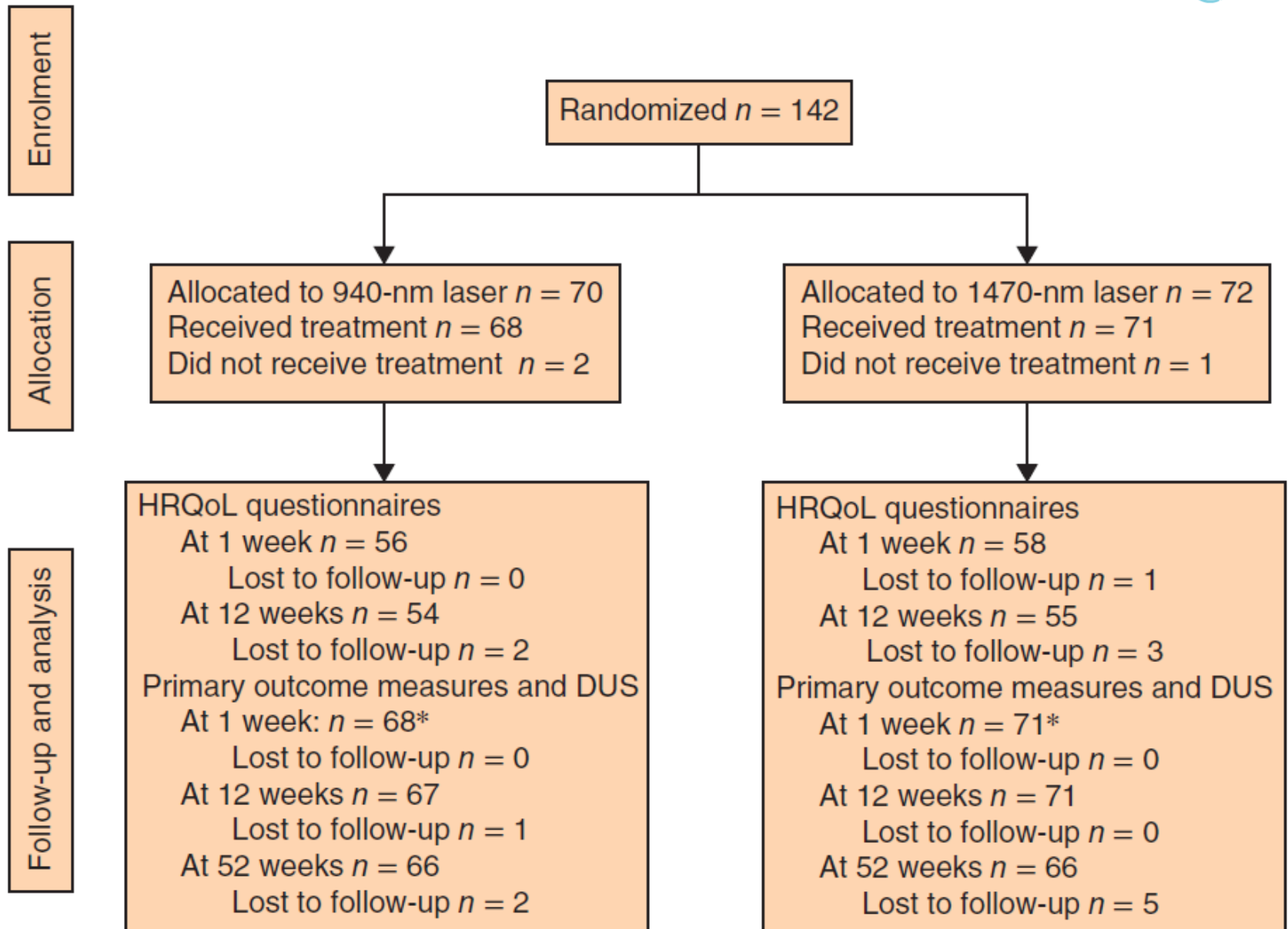
# Methods

- Single center RCT (Erasmus MC)
- 940 nm and 1470 nm EVLA
- Tulip tip fibers, 10 Watt, 40 J/cm
- Inclusion criteria
  - Age > 18 years
  - Informed consent
  - Symptomatic primary incompetent GSV
  - Reflux > 0,5 sec
  - Diameter GSV > 0,5 cm
- Exclusion criteria
  - Acute deep or superficial venous thrombosis
  - Post-thrombotic syndrome obstructive type
  - Agenesis/malformations deep venous system
  - Pregnancy
  - Immobility
  - Arterial insufficiency
  - Allergy to lidocaine



# Methods

- Outcome measures
  - Patient-reported outcomes
    - Pain, satisfaction, analgesia use, limitations in daily life
  - Health-related quality of life (AVVQ en EQ-5D questionnaires)
  - Treatment success
  - Venous Clinical Severity Score (VCSS)
  - Complications
  
- Follow-up
  - 1, 12 and 52 weeks



# Demographics

	940 nm EVLA	1470 nm EVLA	P
<b>Number of legs</b>	70	72	
<b>Number of patients</b>	66	69	
<b>Age (years)</b>	49.8 (36.8-67.4)	54.8 (45.1-65.1)	.551
<b>Gender</b>			.717
Male			
Legs	29 (44)	32 (45)	
Patients	28 (41)	31 (44)	
Female			
Legs	37 (56)	38 (55)	
Patients	41 (59)	40 (56)	

## Demographics (2)

	940 nm EVLA	1470 nm EVLA	P
<b>CEAP classification</b>			<b>.571</b>
C1	0 (0)	0 (0)	
C2	14 (20)	15 (21)	
C3	38 (54)	41 (57)	
C4	15 (21)	14 (19)	
C5	2 (3)	2 (3)	
C6	1 (1)	0 (0)	

## Treatment characteristics

	940 nm EVLA	1470 nm EVLA	P
<b>Side (legs)</b>			<b>.019</b>
Right	37 (53)	34 (33)	
Left	33 (47)	48 (67)	
Unilateral	56 (80)	60 (83)	
Bilateral - same EVLA	8 (11)	6 (8)	
Bilateral - different EVLA	6 (9)	9 (8)	
<b>GSV diameter (mm)</b>	6.0 (6.0-6.8)	6.0 (5.4-6.9)	.410
<b>Saphenofemoral junction</b>			.773
Competent	17 (24)	19 (26)	
Incompetent	53 (76)	53 (74)	
<b>Length of treated GSV (cm)</b>	33.4 (10.1)	33.1 (7.7)	.844
<b>Energy (J/cm)</b>	39.3 (37.8-41.6)	39.0 (36.7-40.7)	.204
<b>Additional phlebectomy</b>	39 (56)	34 (47)	.311



# Results - patient-reported outcomes and HRQoL

	940 nm EVLA	1470 nm EVLA	P
<b>Pain (VAS)</b>	6 (3-8)	3 (2-7)	<b>.004</b>
<b>Satisfaction (VAS)</b>	8 (7-9)	9 (8-10)	.062
<b>Duration analgesia use (days)</b>	2 (0-5)	1 (0-3)	<b>.037</b>
<b>Limited in daily life (days)</b>	0 (0-4)	0 (0-2)	.205
<b>Changes in HRQoL (12 weeks)</b>			
AVVQ	-4.45 (-7.96 to -1.13)	-3.44 (-8.00 to -0.77)	.773
EQ-5D	0.034 (0-0.193)	0.090 (0-0.157)	.619
EQ VAS	0 (-5 to 10)	0 (-2 to 5)	.624

## Results - treatment success and VCSS

	940 nm EVLA	1470 nm EVLA	P
<b>Treatment success</b>			
After 12 weeks	66 of 67 (99; 95-100)	70 of 71 (99; 95-100)	1.000
After 52 weeks	60 of 66 (91; 83-97)	62 of 66 (94; 88-99)	.511
<b>Change in VCSS (12 weeks)</b>	-3 (-5 to -1)	-3 (-5 to -1)	.883

## Results - complications

	940 nm EVLA	1470 nm EVLA	P
<b>After 1 week</b>			
Deep venous thrombosis	0 (0)	0 (0)	-
Superficial venous thrombosis	3 (4)	10 (14)	<b>.050</b>
Nerve injury	0 (0)	0 (0)	-
Skin burn	0 (0)	0(0)	-
Skin infection	0 (0)	1 (1)	.326
Ecchymosis (cm <sup>2</sup> )	0.0 (0.0-0.0)	0.0 (0.0-0.0)	.668
Hyperpigmentation (cm <sup>2</sup> )	0.0 (0.0-0.0)	0.0 (0.0-0.0)	-
<b>After 12 weeks</b>			
Deep venous thrombosis	1 (1)	0 (0)	.486
Superficial venous thrombosis	0 (0)	2 (3)	.497
Nerve injury	1 (1)	0 (0)	.486
Hyperpigmentation	0.0 (0.0-0.0)	0.0 (0.0-0.0)	.916

## Conclusions

- First RCT comparing solely the effect of EVLA wavelength on postoperative patient-reported outcomes
- Patients treated with 1470 nm EVLA reported significantly less pain and a shorter duration of analgesia use 1 week after treatment
- Treatment success, adverse events and improvements in HRQoL and VCSS were comparable between 1470 and 940 nm EVLA

Thank you

