Potential Carcinogenic Effects of Endovenous Laser Ablation

Published: 08-08-2011
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This study will determine the concentration of benzo[a]pyrene before and after EVLA.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Procedural related injuries and complications NEC
Study type	Observational invasive

Summary

ID

NL-OMON36015

Source
ToetsingOnline

Brief title
POCEELA

Condition

- Procedural related injuries and complications NEC
- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Venous varices

Synonym
potential carcinogenic substances during laser treatment

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Raad van bestuur SFG

Intervention

Keyword: cancer, endovenous, EVLA, laser

Outcome measures

Primary outcome

The concentration of benzo[a]pyrene before and after endovenous laser ablation.

Secondary outcome

none

Study description

Background summary

Millions of people worldwide are treated for venous disease. Ablation of the great saphenous vein is one of the most performed treatments. More than 50 years the conventional surgical strip operation was the golden standard. In the past decade the treatment of the great saphenous vein has become more minimally invasive with the use of laser ablation / radio-frequency ablation and cryo ablation. None of these techniques has any evidence benefits above the other.

The most performed minimally invasive treatment of the great saphenous vein nowadays is the endovenous laser ablation (EVLA)
During EVLA a laser catheter is introduced in the great saphenous vein after which it is thermally ablated using a constant temperature around 1000-1200 degrees Celsius for a few minutes.

A panel of experts during the European Vascular Course estimated that more than one million patients will be treated worldwide in 2011 with EVLA.

Because of the continuous promotion of the industry and publication bias it seems that EVLA will become the new 'gold standard' for the treatment of the great saphenous vein.

During EVLA, carbonisation of blood and tissue will occur. Patients recognize this as a taste and smell of 'burned tissue'. This is a systemic effect of carbonized blood passing the nose and tongue mucous membranes.

During (extreme) heat of proteins and/or sugars, polycyclic aromatic hydrocarbons (PAH), heterocyclic amines (HCA) and acrylamide will be formed in

a probably high concentration.

Proven human carcinogenic in the group of PAH is benzo[a]pyrene. Possible human carcinogenic in the group HCA is 2-amino-1-methyl- 6-phenylimidazole [4,5-b] pyridine (PhIP). Acrylamide is possible carcinogenic in humans in high concentrations.
All these substances are carcinogenic in animals,
Maximal Allowable Concentrations (MAC) are defined by the World Health Organization of these substances. It is probably safe to state that the MAC in the human (milieu interne) should not exceed the levels of the environment (milieu externe)

Study objective

This study will determine the concentration of benzo[a]pyrene before and after EVLA.

Study design

This prospective study will be performed in the Sint Franciscus Gasthuis Rotterdam in collaboration with the University of Wageningen.
The aim of this study is to determine the concentration of benzo[a]pyrene before and after EVLA.

A total of 20 patients will be included in this study (10 smokers and 10 non smokers)
It is known that smokers already have elevated concentrations of benzo[a]pyrene. During the first contact by telephone, patients will get study information and a time span of 2 days to determine if they want to participate in the study. The study will be discussed on the outpatient clinic.

Patients will have a medical history taken, physicial examination and a duplex ultrasound.Patients with venous disease and complaints in combination with a duplex proven incompetence of the great saphenous vein will be treated with EVLA.

In all study patients, a blood sample will be collected before and after EVLA (total 2 blood samples). Patients will be further treated according to the EVLA protocol (stockings / paracetamol and a visit at the outpatient clinic after two weeks)

The blood samples will be coded and send to a specialized laboratory at the University of Wageningen.

An independent surgeon (H. Strijdhorst) will be present for further study questions.

The concentration of benzo[a]pyrene will be determined for all study patients before and after EVLA.

There is no need for follow-up.

If extreme concentrations of benzo[a]pyrene occur during EVLA, an international warning should be issued and EVLA treatment should be abandoned.
There are alternatives for the treatment of the great saphenous vein in which lower temperatures (around 100 degreed Celsius) can be used, thereby decreasing or eliminating blood carbonization.

Study burden and risks

none

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

All patients with venous disease and an indication for endovenous laser ablation
- 10 smokers
- 10 non-smokers

Exclusion criteria

All patients who already had an endovenous laser ablation.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2011
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO

Date:	08-08-2011
Application type:	First submission

Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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
CCMO	NL36366.101.11