Treadmill pilot study.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26641

Source
NTR

Health condition

post-thrombotic syndrome, PTS, May-Thurner syndrome, MTS, venous claudication, outflow obstruction, deep venous obstruction, stenting, stent, deep venous thrombosis, DVT

Sponsors and support

Primary sponsor: Maastricht University Medical Centre+
Source(s) of monetary or material Support: Initiator, funded through industry

Intervention

Outcome measures

Primary outcome

Main endpoint is the change in (ambulatory) venous pressure, measured at the dorsal foot vein and common femoral vein. This will be expressed in millimetres mercury.

Secondary outcome

There are various secondary endpoints. Change in pain free walking distance and maximum walking distance will be expressed in both time and distance. Change in diameter/circumference, transverse surface area and flow of the common femoral vein will be expressed in millimetres, square millimetres and millilitres per second, respectively.

Furthermore change in CEAP, Villalta score, venous clinical severity score and generic and disease specific quality of life scores will be assessed. Finally, patency will be assessed.

Study description

Background summary

PTA & stenting in iliofemoral and iliocaval venous obstruction has been proven to be an effective method of treatment with good clinical results. However, no proper investigations have been made to objectify the reduction in (ambulatory) venous hypertension caused by this type of obstruction. Normal ambulatory venous pressure is below 20mmHg, though studies have already shown a linear relationship between the incidence of ulcers and an ambulatory intravenous pressure of more than 30mmHg. We believe that by measuring the (ambulatory) venous pressure before and after stenting, we will gain more knowledge on the hemodynamics of venous disease and its treatment and we will obtain information that might identify patients at risk of stent occlusion or the forming of an ulcer in an early stage. Identifying these patients will most certainly influence preventive treatment in the future.

Objective:

To map the changes in intravenous pressure after PTA & stenting of iliofemoral and iliocaval venous obstruction.

Study design:

Prospective, observational study where patients are their own controls by making use of the waiting time for stenting with an extra test day

Study population:

Patients with an iliofemoral or iliocaval venous obstruction, objectified on duplex ultrasonography and magnetic resonance venography, and the indication for stenting of the obstructed tract(s).

Main endpoint is the change in (ambulatory) venous pressure, measured at the dorsal foot vein and common femoral vein. This will be expressed in millimetres mercury.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients have to make three visits. Each visit will take approximately two hours. During each test day, patients will undergo intravenous pressure measurements in both dorsal foot veins, both common femoral veins and a vein in the left upper arm, which are measured via a venflon needle or microsheath (placed under ultrasound guidance) connected to a pressure transducer; a treadmill test lasting maximally 26 minutes; an air plethysmography, which they need to undergo anyway; and a duplex ultrasound to assess the common femoral vein. This is a very low risk study, since all diagnostic tools that are used or also used in usual clinical practice and given the low risk on mild complications. Patients can experience pain due to the insertion and removal of the venflons/microsheaths and due to compression of the groin after removal of the microsheaths.

Study objective

1. Patients with patent stents will have improved AVP and improved flow in CFV;

2. Patients with stent occlusion will have significantly higher AVPs and lower flow in CFV than patients without stent occlusion;

3. (Pain-free) walking distance will vastly increase;

4. Diameter, circumference and transverse surface area of CFV will hardly increase.

Study design

1. Baseline (2-3 months before stenting);

2. Right before stenting;

3. 2-3 months after stenting.

Intervention

PTA & stenting.

Contacts

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Eligibility criteria

Inclusion criteria

1. Indication for stenting;

2. Minimally 18 years of age;

3. Life expectancy of at least 6 months.

Exclusion criteria

1. Younger than 18 years of age;

2. Life expectancy of less than 6 months;

3. Venous obstruction in the contralateral limb;

4. Peripheral arterial disease;

5. Pregnancy.

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL3790
NTR-old	NTR3963
CCMO	NL44588.068.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A