The use of ultrasound in the therapy of patients with blocked arteries of the lower limb.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27379

Source
NTR

Brief title
MUST

Health condition

peripheral arterial occlusions, peripheral vascular disease, vascular disease, lower limb occlusive disease, acuut perifeer vaatlijden, acute vaatocclusie

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: fund VU University Medical Center sponsor, Lamepro

Intervention

Outcome measures

Primary outcome

Main endpoints will be the duration of thrombolysis needed for uninterrupted flow in the

thrombosed native artery or bypass graft with outflow through at least 1 crural artery and microcirculation of the lower limb as measured by Laser Doppler Flowmetry on the skin of the lower limb. Furthermore, Severe Adverse Events (haemorrhagic complications, allergic reactions, in hospital mortality directly related to the treatment) and amputation-free rate at 6 months.

Secondary outcome

Secondary endpoints will be the success rate, distal thromboembolic complications, other complications, 30 day mortality rate, conversion to open surgery, duration of hospital admission, serum fibrinogen concentrations, pain scores and quality of life.

Study description

Background summary

Acute lower limb occlusion can be caused by a blood clot blocking an artery in the leg. This is an emergency situation that can result in amputation or be life threatening if not treated promptly. Infusion of lytic agents, such as urokinase, can restore blood flow by dissolving the clot as a less invasive alternative to conventional surgical reconstruction, this is called thrombolysis. In comparison with the lysis of small blocked arteries in for example patients with myocardial infarction, larger blocked arteries in vascular surgery patients require higher doses of medicine and treatment over a longer period of time. The technique is less radical than surgery. However, it is time consuming (days), requires repeated angiography for treatment evaluation risking kidney failure and most importantly is accompanied by the risk on major bleeding complications, such as stroke. As a result this leads to high morbidity and mortality rates and a large impact on patient burden. Improvement of this therapy is therefore highly needed.

A potential accelerator of thrombolysis is contrast-enhanced ultrasound. Contrast-agents, initially used as diagnostic tool could also be applied therapeutically to speed up thrombolysis. This could reduce therapy time and lower the required dose of lytic agents leading to a lower risk of bleeding complications and decreased patient burden.

Study objective

The application of contrast-enhanced ultrasound can accelerate thrombolysis in patients with acute peripheral arterial occlusions.

Study design

Acute phase, 3 months, 6 months, 1 year

Intervention

The experimental protocol consists of the standard thrombolysis protocol, i.e. the local placement of a catheter and sheath in the ‘angio-room’ just near the occlusion or thrombus of the affected artery and infusion of urokinase and heparin. In this study additional ultrasound contrast-agents will be intravenously injected and local ultrasound will be applied at the site of occlusion during the first hour of therapy.

Contacts

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Eligibility criteria

Inclusion criteria

• Men and women older than 18 years and younger than 85 years old

• Patients with a maximum of 2 weeks complaints due to lower limb ischemia due to thrombosed/occluded iliofemoral, femoropopliteal or femorocrural native arteries or femoropopliteal or femorocrural venous or prosthetic bypass grafts

• Anatomic suitability duplex ultrasound in case of iliac occlusion

• Patients fit for thrombolysis i.e. with acute lower limb ischemia class I and IIa according to the Rutherford classification (see attachment II)

• Patients understand the nature of the procedure and provide written informed consent before enrollment in the study

Exclusion criteria

• Patients with clinical complaints of acute lower limb ischemia due to thrombosis of the iliofemoral, femoropopliteal or femorocrural native arteries, or femoropopliteal or femorocrural venous or prosthetic bypass grafts more than 2 weeks

• Patients with iliac occlusions anatomically not suitable for duplex ultrasound

• Patients with thrombosed popliteal aneurysms

• Patients with contra-indications for the administration of antiplatelet therapy, anticoagulants or thrombolytics

• Recent (less than 6 weeks) ischemic stroke, cerebral bleeding or myocardial infarction

• Patients with recent (less than 6 weeks) surgery

• Severe hypertension (diastolic blood pressure greater than 110 mm Hg, systolic blood pressure higher than 200 mm Hg)

• Current malignancy or severe comorbid condition with a life expectancy of less than 6 months

• Patients with uncorrected bleeding disorders (gastrointestinal ulcer, menorrhagia, liver failure)

• Women with child-bearing potential not taking adequate contraceptives or currently breastfeeding

• Pregnancy

• Patients who are currently participating in another investigational drug or device study

• Patients younger than 18 years or older than 85 years

• Patients with contra-indications for Luminity microbubbles i.e.

• Hypersensitivity to perflutren or other components of Luminity

• Recent acute coronary syndrome or clinically unstable ischemic cardiac disease, including: evolving or ongoing myocardial infarction, typical angina at rest within last 7 days, significant worsening of cardiac symptoms within last 7 days, recent coronary artery intervention or other factors suggesting clinical instability (for example, recent deterioration of ECG, laboratory or clinical findings), acute cardiac failure, Class III/IV cardiac failure, or severe rhythm disorders

• Patients known to have right-to-left shunts, severe pulmonary hypertension (pulmonary artery pressure >90 mmHg), uncontrolled systemic hypertension, and in patients with GOLD Stage IV COPD, diffuse interstitial fibrosis or adult respiratory distress syndrome.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2016
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	NL4563
NTR-old	NTR4731
Other	:

Study results

Summary results

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