DUET II

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19905

Source
Nationaal Trial Register

Brief title
DUET II

Health condition

Patients with acute and sub-acute (less than 7 weeks) thrombosed infra-inguinal bypass grafts of native arteries

Sponsors and support

Primary sponsor: Sint Antonius Hospital Nieuwegien
Source(s) of monetary or material Support: Sint Antonius Hospital Nieuwegein

Intervention

Outcome measures

Primary outcome

Occurrence of hemorrhagic complications.

Secondary outcome

1. Technical success defined as >95% lysis of thrombosed native artery or bypass within 48 hours

2. Duration of successful catheter-derived thrombolysis needed for uninterrupted flow in the thrombosed arterial segment with outflow via at least one crural artery.

3. Units Urokinase needed for technical success.

4. Distal thrombo-embolic complications

Study description

Study objective

Half dose Urokinase (50.000IE/h) will significantly reduce hemorrhagic complications compared with the standard dose Urokinase (100.000IE/h) with comparable technical success rate

Study design

Follow up visit will be 30 days after treatment

Intervention

50.000IE/h Urokinase

100.000IE/h Urokinase

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with acute and sub-acute (less than 7 weeks) thrombosed infra-inguinal native arteries with ischemic complaints.

2. Patients with acute and sub-acute (less than 7 weeks) thrombosed infra-inguinal venous or prosthetic bypass grafts with ischemic complaints.

3. Limb ischemia class I and IIa according to the Rutherford classification (see below).

4. Patients >18 years and <85 years old.

5. Patients understand the nature of the procedure and provide written informed consent, prior to enrolment in the study

Exclusion criteria

1. Patients with isolated common femoral artery thrombosis including the origin of the superficial femoral artery and/ or profunda femoral artery

2. Patients with clinical complaints of lower limb ischemia due to thrombosis of femoro-popliteal or femoro-crural native arteries or femoro-popliteal and femoro-crural bypass grafts >7 weeks

3. Patients with acute lower limb ischemia class IIb and III according to the Rutherford classification (see below)

4. Patients for whom antiplatelet therapy, anticoagulants or thrombolytic drugs are contraindicated

5. Recent (< 6 weeks) ischemic stroke or cerebral bleeding

6. Patients with recent (<6 weeks) surgery

7. Severe hypertension (diastolic blood pressure >110 mmHg, systolic blood pressure >200 mmHg)

8. Current malignancy

9. Patients with a history of prior life-threatening contrast medium reaction

10. Patients with uncorrected bleeding disorders (GI ulcera, mennorrhagia, liver failure)

11. Female patients of child bearing age not taking adequate contraceptives or currently breastfeeding

12. Pregnancy

13. Any patient considered being hemodynamically unstable at onset of procedure

14. Patients refusing treatment

15. Patients currently participating in another investigational drug or device study that have not completed the entire follow up period

16. Patients < 18 years or >85 years old

17. Severe co-morbid condition with life expectancy < 1 month

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-10-2016
Enrollment:	124
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-10-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44501
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5914
NTR-old	NTR6194
CCMO	NL49466.100.15
OMON	NL-OMON44501

Study results