DUET II

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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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19905

Bron
Nationaal Trial Register

Verkorte titel
DUET II

Aandoening

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

Ondersteuning

Primaire sponsor: Sint Antonius Hospital Nieuwegien
Overige ondersteuning: Sint Antonius Hospital Nieuwegein

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Occurrence of hemorrhagic complications.

Toelichting onderzoek

Doel van het onderzoek

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

Onderzoeksopzet

Follow up visit will be 30 days after treatment

Onderzoeksproduct en/of interventie

50.000IE/h Urokinase

100.000IE/h Urokinase

Contactpersonen

Publiek

Koekoekslaan 1

I.M. van Dop
Nieuwegein 3435CM
The Netherlands

Wetenschappelijk

Koekoekslaan 1

I.M. van Dop
Nieuwegein 3435CM
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-10-2016
Aantal proefpersonen:	124
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-10-2016

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44501
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten