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Standard catheter-directed thrombolysis versus ultrasound-accelerated thrombolysis for thombo-embolic infra-inguinal disease

Submission date 23/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/12/2009	**Overall study status** Completed	
Last Edited 17/03/2015	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL28737.100.09

Study information

Scientific Title
Dutch randomised trial comparing standard catheter-directed thrombolysis versus ultrasound-accelerated thrombolysis for thromboembolic infra-inguinal disease (DUET)

Acronym
DUET

Study objectives
The use of ultrasound-accelerated catheter-derived thrombolysis in patients with recently (between 1 and 7 weeks) thrombosed infra-inguinal native arteries or bypass grafts will significantly reduce (at least 12 hours) therapy time compared to standard thrombolysis alone without increasing complication rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the St. Antonius Hospital Nieuwegein, 13/10/2009, ref: R-09.17A

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Thromboembolic infra-inguinal disease

Interventions
Group A (standard thrombolysis):
During angiography a thrombolysis delivery catheter will be navigated proximally into the thrombus, followed by a control angiography at standardised intervals. During each control angiography the tip of the thrombolysis catheter will be repositioned proximally in the remaining thrombus.

Group B (ultrasound-accelerated thrombolysis):
During angiography a thrombolysis delivery catheter will be navigated into the thrombosed segment with a guide wire in such a way that the treatment zone traverses the entire clot and the tip lies distal to the thrombus. After final positioning, the guide wire will be exchanged for a matching ultrasound-core wire and thrombolytic therapy will be started. Likewise a control angiography will be performed at standardised intervals.

The total duration of follow-up will be 1 month.

Intervention Type
Procedure/Surgery

Primary outcome measure
Duration of catheter-derived thrombolysis needed for uninterrupted flow in the thrombosed infra-inguinal native artery or bypass graft with outflow via at least one crural artery.

Secondary outcome measures
1. Technical success defined as complete lysis of the thrombus of the native artery or bypass graft without distal thrombo-embolic complications
2. Number of units urokinasis needed for uninterrupted flow in the thrombosed infra-inguinal native artery or bypass graft with outflow via at least one crural artery
3. Thrombolysis induced haemorrhagic complications
4. 30-day mortality
5. Duration of hospital admission
6. Costs of hospital admission
7. 30-day patency of the target artery or bypass, as evidenced by magnetic resonance angiography (MRA)
8. Drop of serum fibrinogen concentration to below 1.0 g/L during procedure
7. Conversion to open surgery
8. Distal thromboembolic complications
9. Other complications

Overall study start date
01/11/2009

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. Both males and females, greater than 18 years and less than 85 years old
2. Patients with recently (between 1 and 7 weeks) thrombosed femoro-popliteal or femoro-crural native arteries or femoro-popliteal or femoro-crural venous or prosthetic bypass grafts with ischaemic complaints
3. Patients with acute lower limb ischaemia class I and IIa according to the Rutherford classification
4. Patients understand the nature of the procedure and provide written informed consent, prior to enrolment in the study

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Patients with isolated common femoral artery thrombosis including the origin of the superficial femoral artery and profunda femoral artery
2. Patients with localised (less than 5 cm) emboli/occlusions in the native femoro-popliteal arteries
3. Patients with clinical complaints of acute lower limb ischaemia due to thrombosis of the femoro-popliteal or femoro-crural native arteries or femoro-popliteal or femoro-crural venous or prosthetic bypass grafts less than 1 week and greater than 7 weeks
4. Patients with acute lower limb ischaemia class IIb and III according to the Rutherford classification
5. Patients for whom antiplatelet therapy, anticoagulants or thrombolytic drugs are contra-indicated
6. Recent (less than 6 weeks) ischaemic stroke or cerebral bleeding
7. Patients with recent (less than 6 weeks) surgery
8. Severe hypertension (diastolic blood pressure greater than 110 mmHg, systolic blood pressure greater than 200 mmHg)
9. Current malignancy
10. Patients with a history of prior life-threatening contrast medium reaction
11. Patients with uncorrected bleeding disorders (gastro-intestinal ulcer, menorrhagia, liver failure)
12. Female patients with child bearing potential not taking adequate contraceptives or currently breastfeeding
13. Pregnancy
14. Any patient considered to be haemodynamically unstable at onset of procedure
15. Patients refusing treatment
16. Patients currently participating in another investigational drug or device study that have not completed the entire follow up period
17. Patients less than 18 years or greater than 85 years old
18. Severe co-morbid condition with life expectancy less than 1 month
19. Contra-indication for magnetic resonance imaging (MRI)

Date of first enrolment
01/11/2009

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
St Antonius Hospital Nieuwegein
Nieuwegein
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3435 CM

Sponsor information

Organisation
St Antonius Hospital Nieuwegein (Netherlands)

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Sponsor type
Hospital/treatment centre

Website
http://www.antoniusziekenhuis.nl/

ROR
https://ror.org/01jvpb595

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St Antonius Hospital Nieuwegein (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/01/2011		Yes	No
Results article	results	01/08/2011		Yes	No
Results article	results	01/02/2015		Yes	No