

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

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| Submission date 23/10/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 08/12/2009 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 17/03/2015 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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 urokinase 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Netherlands

3435 CM

Sponsor information

Organisation

St Antonius Hospital Nieuwegein (Netherlands)

ROR

<https://ror.org/01jvpb595>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

St Antonius Hospital Nieuwegein (Netherlands)

Results and Publications

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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Results article | results | 01/08/2011 | | Yes | No |
| Results article | results | 01/02/2015 | | Yes | No |
| Protocol article | protocol | 23/01/2011 | | Yes | No |