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Comparison of the fibrin analysis system (FAS) endoluminal brush with currently accepted practice for restoring patency to blocked or partially blocked haemodialysis catheters.

Submission date 30/09/2005	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2005	**Overall study status** Stopped	
Last Edited 16/12/2010	**Condition category** Urological and Genital Diseases	

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
N0112146492

Study information

Scientific Title

Study objectives
Is the fibrin analysis system (FAS) endoluminal brush better than thrombolytics at restoring patency to blocked haemodialysis catheters?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Haemodialysis

Interventions
There will be two test groups of patients all experiencing a significant reduction in flow rate. This level will be defined as a flow rate that is less than 75% of the best flow rate achieved for that patient with the current catheter. Randomisation enrolment into Test Group 1 or 2 will be carried out by the patient enroller. Two random lists of 30 numbers have been generated. The first was assigned to brush intervention and second to urokinase intervention. The list was combined and ranked. The investigator will be provided with the blind ranked list, and assign each participant to the next sequential number. This code will be broken by an independent trialist, prior to intervention.

Added 20/07/09: the trial was stopped in 2002 due to recruitment issues.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Number of dialysis catheters restored to patency following the intervention.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2002

Completion date
01/11/2004

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Patients on haemodialysis at St Helier Hospital.
Intervention groups:
1. Catheterised haemodialysis patients with a flow rate less than 75% o best flow rate. Note that the same patient may be enrolled several times into the study if flow rate is reduced below 75% several times during the course of the study.
2. Patients new to dialysis or patients that have been on dialysis for a period of time.
3. All catheter types including temporary and permanent catheters.
4. All subjects must have a clinically defined optimal flow rate.
5. All subjects must have an x-ray prior to entry into the study - this would usually be done at the time a catheter is inserted to provide information on the site, tip position and length of catheter inserted.
6. No age restriction, both sexes, no other restrictions due to other illnesses or disorders.

Control Group:
The inclusion criteria for this group are as above, but patient must have flow rates >75% of the best flow rate acheived for that patient with the current catheter. This group will be used to establish baseline complication, time and cost data.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
Subject exclusion criteria from control and intervention groups:
1. Patients with kinked lines
2. Patients with occlusion due to fibrin sheath formation

Date of first enrolment
01/11/2002

Date of final enrolment
01/11/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Epsom and St. Helier NHS Trust
Carshalton
United Kingdom
SM5 1AA

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type

Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Epsom and St Helier University Hospitals NHS Trust (UK), NHS R&D Support Funding

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