ISRCTN35253449 https://doi.org/10.1186/ISRCTN35253449

Prevention of Catheter Lumen Occlusion with recombinant tissue plasminogen activator (rT-PA) versus Heparin (Pre-CLOT): A Double Blind Randomized Trial

Submission date
24/04/2005

Recruitment status
No longer recruiting

Registration date
15/06/2005

Overall study status
Completed

Last Edited
09/02/2011

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Nairne Scott-Douglas

Contact details
Division of Nephrology
University of Calgary
1403 29th St NW
Calgary
Canada
T2N 2T9
+1 403 944 2804
nairne.scott-douglas@calgaryhealthregion.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
Pre-CLOT

Study objectives
To determine if substituting rt-PA for heparin (1 mg per lumen) once per week as a catheter locking solution will decrease the incidence of catheter malfunction compared to locking with heparin alone after each dialysis session.

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)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
End-stage kidney disease

Interventions
rT-PA 1 mg/lumen as a dialysis catheter locking solution used once per week, compared to heparin 5000 units/ml (luminal volume).

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Recombinant tissue plasminogen activator (rT-PA), heparin

Primary outcome measure
Catheter malfunction.

Secondary outcome measures
Catheter related bacteremia.

Overall study start date
01/04/2005

Completion date
31/10/2006

Eligibility

Key inclusion criteria
1. End-stage renal disease (ESRD) patients 18 years of age and older with newly inserted permanent, tunnelled, dual-lumen catheters
2. Naive to study but not naive to catheters
3. Expected to use catheter for at least six months
4. Frequency of dialysis three times per week
5. Baseline international normalised ratio (INR) less than or equal to 1.3
6. Baseline platelet count greater than or equal to 60

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
340

Key exclusion criteria
1. Use of systemic anticoagulation
2. Insertion of catheter by guide-wire exchange
3. Insertion of catheter into femoral vein
4. Current use of antibiotics for catheter-related bacteraemia
5. Major haemorrhage within prior 4 weeks
6. History of intra-cranial or intra-spinal neoplasm

7. Allergy to rT-PA
8. Active pericarditis
9. Weight less than 30 kg
10. Pregnant or lactating
11. Major surgery in past 48 hours
12. Presence of fever

Date of first enrolment
01/04/2005

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
Canada

Study participating centre
Division of Nephrology
Calgary
Canada
T2N 2T9

Sponsor information

Organisation
University of Calgary (Canada)

Sponsor details
1403 29th St NW
Calgary
Canada
T2N 2T9
+1 403 944 2804
nairne.scott-douglas@calgaryhealthregion.ca

Sponsor type
University/education

ROR
https://ror.org/03yjb2x39

Funder(s)

Funder type
Industry

Funder Name
Hoffmann-La Roche Limited (Canada)

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?
Results article	results	11/04/2006		Yes	No
Results article	results	27/01/2011		Yes	No