

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

☒ Results

☐ 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

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

Study type(s)

Prevention

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(s)

Catheter malfunction.

Key secondary outcome(s)

Catheter related bacteremia.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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
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Sponsor information

Organisation
University of Calgary (Canada)

ROR
<https://ror.org/03yjb2x39>

Funder(s)

Funder type
Industry

Funder Name
Hoffmann-La Roche Limited (Canada)

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