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A randomised controlled trial comparing taurolidine-citrate with heparin for locking tunnelled haemodialysis catheters

Submission date	Recruitment status	[X] Prospectively registered
04/07/2006	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/09/2006	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/02/2010	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Study objectives

A new catheter-locking solution containing taurolodine and citrate has been shown to reduce catheter-related bacteraemia in small studies of mainly non-tunnelled catheters. We aim to test whether use of this solution will reduce the incidence of catheter-related bacteraemia in patients with tunnelled dialysis catheters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee for Scotland A (reference: 06/MRE00/43), approval received 13/06/2006.

Primary study design
Interventional

Study design
Interventional randomised double-blind controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic Renal Failure requiring treatment with regular haemodialysis

Interventions
One group will be randomised to receive taurolidine-citrate catheter lock solution and the other heparin 5000 iu/ml catheter lock solution.

Added 18/02/2010: trial was stopped because objectives were no longer viable.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Taurolidine, citrate and heparin

Primary outcome(s)
Rates of catheter-related bacteraemia

Key secondary outcome(s)
1. Rates of catheter occlusion
2. Mortality rate
3. Exit-site infection rates
4. Epoietin requirements
5. Hospitalisation
6. Haemodialysis adequacy

Completion date
01/10/2008

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Chronic renal failure requiring haemodialysis
2. Patients undergoing tunnelled haemodialysis catheter insertion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Aged under 16 years
2. Known intolerance to heparin or taurolidine-citrate
3. Patients receiving antibiotic treatment

Date of first enrolment
01/10/2006

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Renal Unit
Glasgow
United Kingdom
G4 0SF

Sponsor information

Organisation
North Glasgow University NHS Division (UK)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Glasgow Royal Infirmary Renal Unit Research Fund (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration