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

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

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.

Study design
Interventional randomised double-blind 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
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 measure
Rates of catheter-related bacteraemia

Secondary outcome measures
1. Rates of catheter occlusion
2. Mortality rate
3. Exit-site infection rates
4. Epoietin requirements
5. Hospitalisation
6. Haemodialysis adequacy

Overall study start date
01/10/2006

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

Age group
Adult

Sex
Both

Target number of participants
164

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
Scotland

United Kingdom

Study participating centre
Renal Unit
Glasgow
United Kingdom
G4 0SF

Sponsor information

Organisation
North Glasgow University NHS Division (UK)

Sponsor details
Greater Glasgow Health Board
c/o Dr Fiona Graham
East Research and Development Office
4th Floor Walton Building
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Sponsor type
Hospital/treatment centre

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

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