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

Contact name

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Contact details

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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

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 Glasgow Royal Infirmary Glasgow Scotland United Kingdom G4 0SF

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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration