ISRCTN15520615 https://doi.org/10.1186/ISRCTN15520615

Study of the effects of gentamicin locking on bacteraemia rates and function of tunnelled haemodialysis catheters

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/12/2008	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

Protocol serial number
N0077102812

Study information

Scientific Title

Study objectives
Whether use of gentamicin locking of dialysis catheters can influence bacteraemia rates without compromising catheter function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Haemodialysis

Interventions
Patients will be recruited at the time of catheter insertion and randomised to one of two arms. Conventional practice (as defined by use of heparin locking with 5000 u/ml) and locking the catheter with 5 mg/ml of gentamicin in conjunction with heparin.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
We will collect data on a variety of endpoints. Primary end point will be clinical infection rates. Data will also be collected on patency and thrombotic failure of catheters augmented with the data set relating to catheter function and dialysis adequacy that will be captured by the central server.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/04/2003

Eligibility

Key inclusion criteria

Chronic haemodialysis patients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/2002

Date of final enrolment
01/04/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southern Derbyshire Acute Hospitals NHS Trust
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Southern Derbyshire Acute Hospitals NHS Trust (UK)

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	01/08/2004		Yes	No