

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

Submission date
12/09/2003

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
12/09/2003

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
17/12/2008

Condition category
Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2002

Completion date

01/04/2003

Eligibility

Key inclusion criteria

Chronic haemodialysis patients

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

The aim would be to recruit a total of 30-40 patients, who would be studied for 6-12 months.

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

England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Government

Funder Name
Southern Derbyshire Acute Hospitals NHS Trust (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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/08/2004 | | Yes | No |