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Role of antibiotic line locks in the prevention of tunnelled haemodialysis catheter infection: a double-blind, randomised controlled trial

Submission date	Recruitment status	[_] Prospectively registered
07/06/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/02/2013	Infections and Infestations	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
08/05

Study information

Scientific Title

Study objectives
The null hypothesis to be tested is that antibiotic line locks will not reduce the incidence of catheter related blood stream
infection compared with the standard practice of catheter filling with heparin alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Haemodialysis catheter related sepsis

Interventions
Control group will receive usual heparin line locks between dialysis sessions.
Intervention group will receive a line lock containing heparin, vancomycin and gentamicin.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The time in days from insertion of tunnelled haemodialysis catheter (THDC) to first catheter related infection (CRI). CRI will be diagnosed by a combination of clinical suspicion, raised temperature, blood tests (white
cell count and inflammatory markers) and the results of blood cultures from the tunnelled haemodialysis catheter (THDC) and from a peripheral vein.

Secondary outcome measures
1. Mean haemoglobin concentration
2. Mean erythropoietin dose adjusted for body mass
3. Mean serum albumin concentration
4. Mean number of days in hospital per annum
5. Mean number of hospital admissions per annum

Overall study start date
01/08/2004

Completion date
01/08/2006

Eligibility

Key inclusion criteria
All patients requiring insertion of a tunnelled haemodialysis catheter (THDC) for haemodialysis.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Patients on prolonged courses of antibiotics (oral or parenteral) i.e. for greater than 2 weeks. (This may reduce the incidence of CRI and therefore confound the results).
2. Patients with a known allergy to vancomycin or gentamicin
3. Patients known to suffer from heparin induced thrombocytopenia
4. Patients who are pregnant or plan to become pregnant. (Vancomycin and gentamicin are potentially toxic to the fetus).
5. An inability to provide informed consent to participation in the study

Date of first enrolment
01/08/2004

Date of final enrolment
01/08/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Arrowe Park Hospital
Liverpool
United Kingdom
CH49 5PE

Sponsor information

Organisation
Wirral Hospitals NHS Trust (UK)

Sponsor details
Arrowe Park Hospital
Liverpool
England
United Kingdom
CH49 5PE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05cv4zg26

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Funded within our department

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