

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

Submission date
07/06/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
26/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
05/02/2013

Condition category
Infections and Infestations

☐ Individual participant data

☐ 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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Liverpool
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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised double blind controlled trial

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Arrowe Park Hospital

Liverpool

United Kingdom

CH49 5PE

Sponsor information

Organisation

Wirral Hospitals NHS Trust (UK)

ROR

<https://ror.org/05cv4zg26>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Funded within our department

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration