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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/09/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/09/2007	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
18/04/2012	Injury, Occupational Diseases, Poisoning			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Peter McClelland

Contact details

Arrowe Park Hospital
Wirral Hospital NHS Trust
Arrowe Park Road
Upton
Wirral
United Kingdom
CH49 5PE
+44 0151 678 5111
jonathon.davies@whnt.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0280178863

Study information

Scientific Title

Study objectives

Will locking dialysis catheters with antibiotics immediately after placement into the patient reduce infection rate and prolong their life-span?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Single centre double blind randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Injury, Occupational Diseases, Poisoning: Haemodialysis catheter infection

Interventions

1G of vancomycin intraveously before catheter insertion. The catheter site will be inspected at each dialysis and cleaned with 10% aqueous povidone-iodine solution after each dialysis and each time the patient bathes.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Antibiotics

Primary outcome measure

Time in days to catheter-related infections.

Secondary outcome measures

- 1. Haemoglobin concentration
- 2. Erythropoetin dose
- 3. Serum albumin concentration
- 4. Hospital admission rate
- 5. Mean length of hospital stay

Overall study start date

01/06/2006

Completion date

30/06/2008

Eligibility

Key inclusion criteria

Patients aged 18 and above, stratified according to their diabetic status, requiring the insertion of a new tunnelled haemodyalisis catheter.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

80

Key exclusion criteria

- 1. Antibiotics for longer than 2 weeks
- 2. Pregnancy or planned pregnancy
- 3. Pregnancy
- 4. Allergy to vancomycin or gemtamicin
- 5. History of heparin induced thrombocytopaenia

Date of first enrolment

01/06/2006

Date of final enrolment

30/06/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Arrowe Park Hospital

Wirral United Kingdom CH49 5PE

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Wirral Hospitals NHS Trust

Funder Name

NHS R&D Support Funding

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	01/01/2008		Yes	No