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Double-blind clinical trial of taurolidine-citrate for the prevention of infection in patients using tunnelled lines for haemodialysis

Submission date 09/08/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/09/2009	**Overall study status** Completed	
Last Edited 28/07/2010	**Condition category** Infections and Infestations	

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

N/A

Study information

Scientific Title
Taurolidine-citrate catheter locks for the prevention of bacteraemia in patients using tunnelled intravascular catheters for haemodialysis: a randomised double-blind controlled trial

Study objectives
The primary aim of this study is to evaluate the feasibility, efficacy and cost-effectiveness of taurolidine line locks in the prevention of bacteraemia in haemodialysis patients using tunnelled lines starting at the time of line insertion and whether use of taurolidine from the time of line insertion is associated with an increased need for thrombolytic therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cumbria and Lancashire B Research Ethics committee approved on the 4th July 2006 (ref: 06 /Q1309/30)

Study design
Randomised double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Catheter-related bacteraemia

Interventions
Patients will randomised to receive either taurolidine-citrate or standard heparin (5000 IU/ml) line locks at the time of catheter insertion and after every dialysis until an end-point of the trial. Taurolidine will be supplied as 1.35% taurolidine and 4% citrate (TauroLock™, Tauropharm AG). Heparin will supplied as heparin sodium, Ph Eur (porcine) at 5000 IU/L with 1% benzylic acid as preservative (Braun AG). This trial will be completed six months after the recruitment of the last participant.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Taurolidine-citrate, heparin

Primary outcome measure
1. 'Intention to treat' analysis of symptomatic and asymptomatic bacteraemic episodes. A bacteraemic episode will be defined by a single positive blood culture. Symptoms will be judged clinically on the basis of fever or rigors associated with dialysis. Measured by a positive blood culture at the time when the patient has relevant symptoms
2. A comparison of the unassisted line patency rate between the two treatment groups. This will be based on the need for thrombolytic therapy or radiological intervention. Detected by a requirement to use of thrombolytic therapy and the date when this happened.

Secondary outcome measures
1. The type of bacterium, outcome of treatment with antibiotics and relapse rate in those patients with proven infection
2. C-reactive protein concentrations
3. Haemoglobin concentrations, measured monthly
4. Erythropoietin requirement, recorded every two weeks
5. Blood flows, recorded every two weeks
6. Electron microscopy of removed lines to look for Biofilm

Overall study start date
01/11/2006

Completion date
30/09/2008

Eligibility

Key inclusion criteria
1. Adult patients (aged greater than 18 years), either sex
2. Requirement for dialysis using a tunnelled dialysis line
3. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
50 patients per group (total: 100 patients)

Key exclusion criteria
1. Children aged less than 18 years
2. Unable to give informed consent
3. Positive blood culture in previous seven days
4. Unstable bleeding diathesis or hypercoagulable state

Date of first enrolment
01/11/2006

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Renal Unit
Preston
United Kingdom
PR2 9HT

Sponsor information

Organisation
Lancashire Teaching Hospitals NHS Foundation Trust (UK)

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England
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Sponsor type

Hospital/treatment centre

Website
http://www.lancsteachinghospitals.nhs.uk/

ROR
https://ror.org/02j7n9748

Funder(s)

Funder type
Government

Funder Name
Lancashire Teaching Hospitals NHS Foundation Trust (UK) - internal funding

Funder Name
Central Manchester University Hospitals NHS Foundation Trust (UK) - internal funding

Funder Name
Royal Liverpool Hospital NHS Trust (UK) - internal funding

Funder Name
North West Kidney Research Association (UK) - small grant from the Preston Branch

Funder Name
Liverpool Regional Dialysis Unit Fund (UK) - small grant

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	01/06/2010		Yes	No