ISRCTN51902376 https://doi.org/10.1186/ISRCTN51902376

# 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

**Registration date**
18/09/2009

**Overall study status**
Completed

**Last Edited**
28/07/2010

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## 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)

## Primary study design
Interventional

## Study design
Randomised double-blind controlled trial

## Study type(s)
Treatment

## 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(s)
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.

### Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### 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
United Kingdom

England

**Study participating centre**
**Renal Unit**
Preston
United Kingdom
PR2 9HT

# Sponsor information

**Organisation**
Lancashire Teaching Hospitals NHS Foundation Trust (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

## 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 |