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Study of need for thrombolytic therapy and incidence of bacteremia using taurolidine-citrate-heparin, taurololidine-citrate and heparin catheter locks in patients treated with haemodialysis

Submission date 19/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/04/2011	**Overall study status** Completed	
Last Edited 25/04/2014	**Condition category** Surgery	

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
Evaluating the need for thrombolytic therapy and incidence of bacteremia using taurolidine-citrate-heparin, taurololidine-citrate and heparin catheter locks in patients treated with haemodialysis: An open-label, observational study with retrospective comparator groups

Study objectives
To determine whether addition of 500 units/ml of heparin to taurolidine-citrate catheter locks reduces the need for thrombolysis compared to taurolidine-citrate in haemodialysis patients using tunnelled intravascular catheters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This is an observational study based on routine clinical practice, which does not require ethics approval.

Study design
Open-label observational study with retrospective comparator groups

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Tunnelled intravascular catheters for haemodialysis

Interventions
Interdialytic locking with taurolidine-citrate-heparin (1.35% taurolidine, 4% citrate and 500 U/ml heparin) compared to taurolidine-citrate (1.35% taurolidine, 4% citrate) and heparin 5000U/ml.

Total duration of follow up is10 months.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. Time to first use thrombolysis for poor catheter flows
2. Time to first bacteremia

Secondary outcome measures
1. Incidence of gram-negative, gram-positive and staphylococcus aureus bacteraemia per 1000 catheter-days
2. Catheter survival after censoring for elective removal

Overall study start date
01/03/2009

Completion date
31/12/2010

Eligibility

Key inclusion criteria
All adult haemodialysis patients requiring an internal jugular intravascular catheter for haemodialysis dialysing at single Haemodialysis Centre in NorthWest England.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
106

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/03/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Renal Unit
Preston
United Kingdom
PR2 9HT

Sponsor information

Organisation
Lancashire Teaching Hospitals NHS trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02j7n9748

Funder(s)

Funder type
Government

Funder Name
Lancashire Teaching Hospitals NHS trust (UK)

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	01/03/2012		Yes	No