

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

Submission date 19/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/04/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/04/2014	Condition category Surgery	<input type="checkbox"/> 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

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, taurolidine-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 is 10 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)

Sponsor details

Sharoe Green Lane

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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