

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

Registration date
18/09/2009

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
28/07/2010

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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)

Sponsor details

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Preston

England

United Kingdom

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+44 (0)1772 716565

laurie.solomon@lthtr.nhs.uk

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