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Cathasept for prevention of catheter colonisation

Submission date	Recruitment status	[_] Prospectively registered
23/03/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/04/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/03/2016	Infections and Infestations	

Plain English summary of protocol

Background and study aims
People whose kidneys fail rely on dialysis machines (usually three times weekly) to clean their blood from waste products. Dialysis treatment requires access to the patient's circulation, which is sometimes achieved by inserting a plastic tube (catheter) into a major vein in the body. Two major complications are associated with the use of catheters: catheter occlusion due to clot formation inside or outside the catheter lumen, and infection that can lead to serious blood poisoning (bloodstream infection), which is a major cause of death in this group of patients. Usually an anticoagulant solution called Heparin is instilled and locked inside the catheter between dialysis sessions to prevent catheter occlusion. Research has shown that Heparin encourages bacterial growth on the catheter's surface and may contribute to infection. A lock solution that prevents catheter occlusion and infection would be ideal to address the two major complications associated with catheters use. Cathasept lock solution has anticoagulant and anti-microbial effects. The aim of this study is to assess the effectiveness of Cathasept line lock to reduce microbial colonization of hemodialysis catheters.

Who can participate?
People receiving dialysis treatment at four dialysis centers in the Yorkshire region in the UK.

What does the study involve?
Patients who were deemed eligible and provided informed consent, were randomly assigned to either continue Heparin locks or to receive Cathasept locks. Participants were regularly checked for signs of infection and were tested weekly for catheter infection by obtaining 1 ml of blood through the catheter lumens and sent for microbial culture.

What are the possible benefits and risks of participating?
Benefits include reduction in catheter-related infections with lower hospital admissions, improved general wellbeing, and reduced cost. However, Cathasept may not be as effective an anticoagulant as Heparin, which may result in higher incidence of catheter occlusion.

Where is the study run from?
Four dialysis centers in the Yorkshire region in the UK

When is the study starting and how long is it expected to run for?
August 2006 to October 2008

Who is funding the study?
Yorkshire Kidney Research Fund (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
337.23

Study information

Scientific Title
Multi-center, prospective, randomised, controlled study to assess the efficacy of Cathasept line lock to reduce microbial colonization of tunneled hemodialysis catheters

Study objectives
Null hypothesis: There is no statistically significant difference in the percentage of cases with colonised catheters between the Cathasept group and the heparin group.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Leeds (West) Medical Research Ethics Committee, 07/03/2006, ref: 05/Q1205/241

Study design
Multi-center prospective randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Microbial colonisation of tunnelled haemodialysis catheters

Interventions
Eligible participants were randomly assigned to have their catheter locked with standard Heparin 5000 units/ml (control group) or with Cathasept (intervention group). Participants underwent weekly culture of 1 ml of blood aspirated from their catheters to check for microbial colonisation and were monitored for signs of infection and catheter dysfunction. Participants were followed up until their catheter was removed or for 8 months if the catheter was not removed.

Intervention Type
Device

Primary outcome measure
Incidence rate of clinically significant microbial colonization of t-HDC per 1000 catheter-days, defined as TCQBC yielding ≥1000 CFU/ml of bacteria or yeast.

Secondary outcome measures
1. Incidence rate of CRBSI
2. Number of dialysis sessions where the prescribed blood flow was achieved
3. Incidence rate of interventions to improve catheter patency including intra-catheter lock or infusion of thrombolytic agents
4. Difference between both groups for hemoglobin, hs-CRP, serum ferritin, Kt/V, and iron and erythropoietin-stimulating requirements. Kt/V is a measurement used to quantify dialysis

treatment adequacy (K is the dialyzer clearance of urea, t is the time spent on dialysis that day and not the prescribed time on dialysis, and V is the volume of distribution of urea which is approximately equal to total body water).

Overall study start date
01/08/2006

Completion date
31/10/2008

Eligibility

Key inclusion criteria
1. Able to provide informed consent
2. History of established renal failure (ERF)
3. Starting or undergoing hemodialysis using a t-HDC in an internal jugular or subclavian vein

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
140

Key exclusion criteria
1. Any medical, social or psychological condition that would compromise participation and follow-up in the study
2. Females who were pregnant or lactating
3. Patients who had a tunneled catheter with an expected duration of placement or use of less than 60 days
4. Patients enrolled in another clinical study, or had participated in the study
5. Life expectancy of less than 3 months
6. Patients with existing tunneled central venous catheters who had positive blood cultures or received antimicrobial therapy, including antibiotic lock solution and/or antimicrobial catheters, for documented or suspected CRBSI within 14 days prior to enrolment
7. Evidence of systemic infection or catheter exit site infection at the time of enrolment
8. Patients with colonized catheters (screening quantitative through catheter blood cultures (QTCBC) yielding >20 cfu/ml bacteria or yeasts)
9. Patients whose catheters demonstrated signs of dysfunction in two or more dialysis sessions during the last two weeks prior to enrolment. These signs were defined as:
9.1. Blood flow rate < 200 ml/min, or prescribed blood flow rate was not achieved, OR
9.2. Elevated venous pressure (>250 mmHg), or negative arterial pressure of greater than (-250 mmHg), OR
9.3. Line reversal (using the arterial port to aspirate and the venous port to return blood)
10. A known sensitivity to heparin, disodium EDTA, or natural rubber latex

Date of first enrolment
01/08/2006

Date of final enrolment
31/08/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Teaching Hospitals NHS Trust
United Kingdom
LS9 7TF

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
United Kingdom
BD5 0NA

Study participating centre
York Teaching Hospital NHS Foundation Trust
United Kingdom
YO31 8HE

Study participating centre
Hull and East Yorkshire Hospitals NHS Trust and Hull York Medical School
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Tyco Healthcare Group LP d/b/a Covidien (USA)

Sponsor details

Mansfield
Mansfield
United States of America
02048

Sponsor type
Industry

ROR
https://ror.org/00grd1h17

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Kidney Research Fund

Results and Publications

Publication and dissemination plan
The study is currently being considered for publication - a revised manuscript has been submitted.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2015		Yes	No