# Cathasept for prevention of catheter colonisation

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

### 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 antimicrobial 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? Dr Muhammad Kanaa muhammad.kanaa@dbh.nhs.uk

### **Contact information**

**Type(s)** Scientific

**Contact name** Dr Muhammad Kanaa

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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 followup 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</li>
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