# Trisodium citrate versus heparin for locking tunnelled haemodialysis catheters: a randomised controlled trial

Submission date	Recruitment status	Prospectively registered
30/09/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	☐ Results
Last Edited	Condition category	Individual participant data
08/09/2014	Urological and Genital Diseases	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr M Abdalla

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0158153706

# Study information

#### Scientific Title

#### **Study objectives**

To compare the effectiveness of 46.7% trisodium citrate versus unfractionated heparin (5000 IU /ml) in preventing clotting of tunnelled haemodialysis catheters.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Prevention

#### Participant information sheet

# Health condition(s) or problem(s) studied

Renal failure

#### Interventions

Trisodium citrate versus heparin for locking tunnelled haemodialysis catheters.

#### Intervention Type

Drug

#### Phase

Not Applicable

# Drug/device/biological/vaccine name(s)

Trisodium citrate, unfractionated heparin

## Primary outcome measure

Catheter blood flow of less than 250 ml/minute and/or venous pressure of more than 260 mmHg, persisting for one hour/session, in two consecutive sessions.

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/02/2005

#### Completion date

01/08/2006

# Eligibility

#### Key inclusion criteria

Any patient who require a new tunnelled catheter for haemodialysis. Patients fall into three groups:

- 1. Patients who present to the kidney unit of the UHNS with kidney failure needing maintenance haemodialysis
- 2. Patients who have to switch from peritoneal to haemodialysis because of problems with their peritoneal dialysis
- 3. Existing haemodialysis patients who need tunnelled catheters because their arterivenous fistulas or tunnelled catheters have failed

The decision to place a tunnelled dialysis catheter is made by one of the renal consultants entirely on the basis of clinical need. Patients will be invited to take part prior to insertion of the tunnelled dialysis catheter. Randomisation will be by sealed envelopes. The only differences in dialysis care that patients will have is the locking agent, otherwise patients will have the same treatment whether they are dialysing in our main renal unit in Stoke or our two satellite units at Stafford and Leighton. They will be followed up and all dialysis-related issues will be documented as per current practice.

## Participant type(s)

**Patient** 

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### Target number of participants

Not provided at time of registration

#### Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

01/02/2005

# Date of final enrolment

01/08/2006

# Locations

#### Countries of recruitment

England

**United Kingdom** 

Study participating centre Nephrology Department Stoke-on-Trent

Stoke-on-Trent United Kingdom ST4 7LN

# Sponsor information

### Organisation

Department of Health

## Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

#### Sponsor type

Government

#### Website

http://www.dh.gov.uk/Home/fs/en

# Funder(s)

## Funder type

Government

#### **Funder Name**

# **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