

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s))

Not provided at time of registration

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 arteriovenous 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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Nephrology Department

Stoke-on-Trent

United Kingdom

ST4 7LN

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

North Staffordshire Research and Development Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration