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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	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M Abdalla

Contact details
Nephrology Department
North Staffordshire Royal Infirmary
Princes Road
Hartshill
Stoke-on-Trent
United Kingdom
ST4 7LN

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
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