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Prospective randomised trial of laparoscopic versus closed insertion of Tenckhoff catheters for peritoneal dialysis access

Submission date 12/09/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 22/11/2011	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0544093499

Study information

Scientific Title

Study objectives
Laparoscopic versus closed insertion of peritoneal dialysis 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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Peritoneal dialysis

Interventions
Patients who are admitted to Addenbrooke's Hospital for insertion of peritoneal dialysis catheters will be randomised to undergo the procedure by one of the two methods:
1. Percutaneous closed insertion under local anaesthesia in the ward
2. Laparoscopic insertion under general anaesthesia in the main operating theatre

The failure rates and complications of the two procedures will be compared. Both these techniques are normally done in this hospital. The only additional requirement from the patient is consent for randomisation.

Trial stopped due to poor recruitment.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
11/09/2000

Completion date
11/09/2003

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
100 patients (PROJ)

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
11/09/2000

Date of final enrolment
11/09/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Box No 210
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

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