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Study to compare the clinical outcomes of coiled-end versus straight-end Swan-Neck peritoneal dialysis (PD) catheters

Submission date	Recruitment status	[_] Prospectively registered
16/02/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/02/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/01/2012	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Nan Chen

Contact details
197 Ruijin Er Road
Shanghai
China
20025

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NCT31143456

Study information

Scientific Title
A prospective, randomised, controlled trial to compare the clinical outcomes of coiled-end versus straight-end Swan-Neck peritoneal dialysis (PD) catheters in Chinese Han population

Study objectives
A reliable permanent access is the key factor in the successful delivery of peritoneal dialysis (PD).

The main objective of catheter design is to reduce the risk of mechanical and infectious complications. Variations in the design of peritoneal catheters include different numbers of cuffs (single vs double), different shapes of subcutaneous paths (permanently-bent Swan neck catheter vs straight Tenckhoff catheter) and different shapes of intra-abdominal segments (straight vs coiled).

A recent systematic review demonstrated that the benefits of various design types have been studied poorly.Most published studies are limited by a small sample size and various design problems, such as lack of stratification by surgeon and presence of several interventions (eg. single vs double cuff, Swan-Neck vs Tenckhoff, Moncrief-Popovich vs conventional insertion technique, median vs lateral insertion site, etc). As a result, the International Society for Peritoneal Dialysis (ISPD) is unable to provide definitive guidelines for catheter choice. Moreover, most studies have been performed in Caucasians, and there is general lack of data relevant to Asian populations. It is generally believed that this design allows for less dialysate inflow pain and less propensity for catheter migration. However, two recent studies have suggested that coiled catheters may be associated with a greater rate of drainage dysfunction due to catheter tip migration and may require replacement more frequently compared to straight catheters. These observations prompted our randomised controlled trial (RCT) with the primary hypothesis that coiled-end catheters may be more prone to catheter tip migration and resultant catheter dysfunction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hospital Ethics Committee for Human Research, approved on 14th May 2006, ref no: RJYY200605005

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
End stage renal disease requiring renal replacement therapy

Interventions
The patients of two groups were randomised to be inserted with a coiled or a straight Swan-neck peritoneal catheter. After the catheter insertion, the twin bag system, lactate dialysate (Dianeal, Baxter, China) with glucose concentration 1.5% or 2.5%, with a dialytic dose of 6-8 L per day was used.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Catheter tip migration defined as catheter tip located above the pelvic brim on the abdominal X-ray with associated catheter dysfunction

Secondary outcome measures
1. All-cause catheter failure (defined by a necessity to remove or reposition the catheter by surgical methods)
2. Catheter related infections (including peritonitis, exit-site infection and tunnel infection)
3. Technique survival (defined as time to permanent transition to haemodialysis) and overall patient survival

Overall study start date
01/10/2006

Completion date
28/02/2008

Eligibility

Key inclusion criteria
1. Age between 18 and 80
2. Presence of end stage renal disease (ESRD)
3. Initiation of Continuous Ambulatory Peritoneal Dialysis (CAPD) therapy in our hospital
4. Expected survival greater than 6 months
5. Provision of informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 patients with coiled end catheter and 40 patients with straight end catheter

Key exclusion criteria
1. Unstable or poorly controlled coronary artery disease
2. Severe congestive heart failure (New York Heart Association Grade III or IV)
3. Severe chronic respiratory disease, malignant disease, clinically significant hepatic disease, acute renal failure and psychiatric disease
4. Women who were pregnant or lactating

Date of first enrolment
01/10/2006

Date of final enrolment
28/02/2008

Locations

Countries of recruitment
China

Study participating centre
197 Ruijin Er Road
Shanghai
China
20025

Sponsor information

Organisation
Shanghai Ruijin Hospital, Shanghai Jiaotong University, School of Medicine (China)

Sponsor details
197 Ruijin Er Road
c/o Prof Nan Chen
Shanghai
China
20025

Sponsor type
University/education

ROR
https://ror.org/01hv94n30

Funder(s)

Funder type
Government

Funder Name
Leading Academic Discipline Project of Shanghai Health Bureau (China) (05III 001 and 2003ZD002)

Funder Name
Shanghai Leading Academic Discipline Project (China) (T0201)

Funder Name
The National Natural Science Foundation (China) (81000295)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2011		Yes	No