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Clinical benefits and safety of a continuous ambulatory peritoneal dialysis (CAPD) technique with one icodextrin-containing and two glucose-containing dialysates a day in incident CAPD patients

Submission date
01/06/2011

Recruitment status
No longer recruiting

Registration date
21/06/2011

Overall study status
Completed

Last Edited
20/10/2017

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Peritoneal dialysis is a type of dialysis that uses the inside lining of the abdomen (the peritoneum) as a filter to remove waste products and excess fluid from the blood when the kidneys stop working properly. Continuous ambulatory peritoneal dialysis (CAPD) is where the blood is filtered several times during the day. The conventional CAPD technique involves four exchanges of glucose dialysate fluid per day. Icodextrin is a glucose polymer that has been developed to improve filtration with fewer side effects (e.g. high blood sugar) than glucose solutions. A three daily exchange-CAPD technique using one icodextrin-containing and two glucose-containing dialysates may better preserve residual kidney function and be less harmful. The aim of this study is to evaluate the benefits of a three daily exchange-CAPD technique using one icodextrin-containing and two glucose-containing dialysates in new CAPD patients.

Who can participate?
Patients with end-stage kidney disease who are starting CAPD

What does the study involve?
After joining the study, participants use four exchanges of glucose-containing dialysates a day. After one month, they are randomly allocated to one of two groups. One group uses four exchanges of glucose-containing dialysates a day. The other group uses one icodextrin solution and two glucose-based dialysates a day. All participants attend visits for tests every month up to 12 months. Residual kidney function and other factors are assessed at the start of the study and after 6 and 12 months.

What are the possible benefits and risks of participating?
There are no risks for the participants because the participants are patients who are starting CAPD and therefore have residual kidney function.

Where is the study run from?
The eight affiliated hospitals of the Catholic University of Korea (South Korea)

When is the study starting and how long is it expected to run for?
April 2008 to October 2010

Who is funding the project?
The Catholic University of Korea (South Korea)

Who is the main contact?
Dr Yong-Soo Kim

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
KCMC08MI035

Study information

Scientific Title
Comparison of benefits and safety between a CAPD technique with one icodextrin containing and two glucose containing dialysate a day and a CAPD technique with four exchanges of glucose-containing dialysates: a multicentre, prospective, randomized controlled trial

Study objectives
The use of more biocompatible solutions has been suggested to preserve peritoneal membrane integrity. Icodextrin is a glucose polymer developed to enhance ultrafiltration in patients with high solute transport. The high molecular weight of icodextrin creates colloid oncotic pressure, which promotes ultrafiltration for a longer time than does dextrose. In addition, the lower carbohydrate load of icodextrin induces less hyperglycemia, hyperinsulinemia, and dyslipidemia than glucose solutions.

Based on the characteristics of icodextrin, we hypothesized that a three daily exchange-CAPD technique using one icodextrin-containing and two glucose-containing dialysates may better preserve residual renal function and may be more biocompatible compared to the CAPD technique using four exchanges of glucose solutions in new CAPD patients, who have residual renal function (RRF). The purpose of the present study was to evaluate the clinical benefits of a three daily exchange-CAPD technique using one icodextrin-containing and two glucose-containing dialysates in terms of residual renal function, biocompatibility, and dialysis adequacy in incident CAPD patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Catholic Medical Center, Office of Human Research Protection, 14/03/2008, Protocol number: KCMC08MI035

Study design
Multicentre prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
End stage renal disease/ continuous ambulatory peritoneal dialysis (CAPD)

Interventions
1. After enrollment, patients used four exchanges of glucose-containing dialysates a day
2. After one month, patients were randomly assigned to one of the two groups
3. Control group (GLU) used four exchanges of glucose-containing dialysates a day
4. Treatment group (ICO) used one icodextrin solution for the long dwell (12h) and two exchanges of glucose-based dialysates a day
5. Liberal use of 1.5%, 2.5%, or 4.25% glucose-based dialysates was allowed in both groups to achieve adequate control of edema and blood pressure
6. Visits were scheduled every month, and clinical evaluations were done in each visit
7. Peritoneal equilibration test was done at 0 month. Laboratory assessments were done at 0 month and every three months for hematological data as well as serum chemistry data
8. Urine and peritoneal effluent samples were analyzed every six months for glucose, urea, and creatinine levels
9. 24h peritoneal effluent samples were analyzed for cancer antigen 125 (CA125) levels
10. Plain radiographs for chest were taken every six months
11. The study period was 12 months after randomization

Intervention Type
Procedure/Surgery

Primary outcome(s)

1. Residual renal function (24h urine volume and renal creatinine clearance) at baseline, 6 months and 12 months
2. Ultrafiltration volume at baseline, 6 months and 12 months
3. Peritoneal glucose absorption at baseline, 6 months and 12 months
4. Peritoneal effluent CA125 levels at baseline, 6 months and 12 months

Key secondary outcome(s))
1. Dialysis adequacy (weekly Kt/Vurea and normalized protein equivalent of nitrogen appearance) at baseline, 6 months and 12 months
2. Use of anti-lipid drugs at baseline, 6 months and 12 months
3. Insulin requirements at baseline, 6 months and 12 months
4. Cardiothoracic index on chest radiographs at baseline, 6 months and 12 months
5. Body weight at baseline, 6 months and 12 months
6. Events of peritonitis during 12 months
7. Events of cardiovascular disease during 12 months

Completion date
20/10/2010

Eligibility

Key inclusion criteria
End-stage renal disease patients starting continuous ambulatory peritoneal dialysis (CAPD)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Bedridden status
2. Dependency on tube feeding
3. Advanced liver cirrhosis
4. Current malignancy

Date of first enrolment
14/04/2008

Date of final enrolment
20/10/2010

Locations

Countries of recruitment
Korea, South

Study participating centre
Seoul St. Mary's Hospital
Seoul
Korea, South
137-701

Sponsor information

Organisation
The Catholic University of Korea (Korea, South)

ROR
https://ror.org/01fpnj063

Funder(s)

Funder type
University/education

Funder Name
Catholic University of Korea

Alternative Name(s)
The Catholic University of Korea, , CUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Korea, South

Results and Publications

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	01/09/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes