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Cardiac function in automated peritoneal dialysis patients

Submission date	Recruitment status	[_] Prospectively registered
23/03/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/05/2019	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
In end-stage kidney disease, the kidney is unable to remove waste from the blood. Consequently, replacement therapy for kidney function has to be initiated. Peritoneal dialysis (PD) is one of several kidney replacement therapies. A PD catheter (tube) is implanted into the abdomen before PD commencement. Then glucose (sugar) solution is pumped into the abdominal cavity using the PD catheter and is allowed to remain for for 4-6 hours before being pumped out. Generally, the procedure has to be repeated 4 times a day. Uremic (nitrogen-containing) toxins and excessive water are removed via osmosis by glucose solution. Another type of PD therapy is called automated peritoneal dialysis (APD), in which a machine pumps PD solution in and out automatically in the night or daytime. The therapeutic duration is around 8-12 hours depending on doctor prescription. The benefit is the avoidance of frequent manual exchanges by patients especially in the daytime. The capacity of fluid removed by glucose solution varies depending on individual's condition. There might be a fluid burden to the heart if not enough water is removed during PD. Icodextrin is a glucose polymer (chain) demonstrating a high capacity for water removal from the abdominal cavity and a long dwell time (10-12 hours retention in the abdominal cavity). Therefore, the proposal is that icodextrin use might achieve better water removal than glucose PD solution, and result in better heart function. The aim in the present trial is attempt to compare heart function between two groups, icodextrin solution or glucose solution in people undergoing APD.

Who can participate?
Adults treated with PD for end-stage kidney disease

What does the study involve?
The trial is two arms, one uses icodextrin solution in the daytime, another arm uses glucose solution in the daytime. All participants use glucose solution for PD therapy in the night with APD regimen.

What are the possible benefits and risks of participating?
The expected benefit in this trial is better water removal, resulting in better heart function in

participants in the icodextrin group. Reported side effects in icodextrin solution are rare, but include allergic skin reactions and abdominal swelling. The side effect is easily controlled by stopping icodextrin solution use and managing symptoms.

Where is the study run from?
PD unit in Kaohsiung Chang Gung Memorial Hospital in Taiwan

When is the study starting and how long is it expected to run for?
The trial began in June 2009 and was completed in May 2015.

Who is funding the study?
This work is supported by Baxter-Clinical Evidence Council (CEC) Fund

Who is the main contact?
Dr Jin-Bor Chen
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
08CEC2AP002

Study information

Scientific Title
A longitudinal changes of cardiac function with icodextrin in automated peritoneal dialysis patients

Study objectives
We hypothesized that the use of icodextrin (ICO) in peritoneal dialysis therapy has an advantage in cardiac function via sustained ultrafiltration compared to glucose (GLU)-based solution.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol was approved by the Committee on Human Research at Kaohsiung Chang Gung Memorial Hospital (98-0390B)(March,2009)

Study design
Single-center randomized case-control 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
End-stage kidney disease patients treated with automated peritoneal dialysis (APD)

Interventions
We used a purposive sampling method to enroll study participants in the outpatient department. After the study protocol was explained and informed consent was obtained, we used a computer-generated block randomization method to categorize enrolled participants into two groups. All of the participants underwent nocturnal APD with varying concentrations of glucose-based PD solutions and icodextrin PD solution depending on the prescription from their respective nephrologists. The duration of treatment is 2 years in each subject, and length of follow-up is 2 years.

Intervention Type
Other

Primary outcome measure
Cardiac structure and function are measured using echocardiography at baseline, 1 year and 2 years.

Secondary outcome measures
Hospitalization for heart failure in the study period measured by patient medical records review.

Overall study start date

01/03/2009

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Agreed to receive nocturnal APD regimen with daytime dwell of at least 10 h

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Total final enrolment
43

Key exclusion criteria
1. Starch allergy
2. Glycogen storage disease
3. Life expectancy of <12 months
4. Serious disease within 30 days before randomization
5. Pregnancy or lactation
6. Significant psychiatric disorder that would interfere with their ability to provide informed consent and/or comply with the study procedures.

Date of first enrolment
31/03/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Taiwan

Study participating centre
Kaohsiung Chang Gung Memorial hospital
123 Da Pei Rd, Niao Song Dist

Kaohsiung
Taiwan
833

Sponsor information

Organisation
Baxter

Sponsor details
not available in website
not available in website
United States of America
not available in website

Sponsor type
Industry

Website
baxter.com

ROR
https://ror.org/02d6ew870

Funder(s)

Funder type
Not defined

Funder Name
Baxter-Clinical Evidence Council (CEC) Fund

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jin-Bor Chen (chenjb1019@gmail.com) until December 2019.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/05/2018	16/01/2019	Yes	No