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A new peritoneal dialysis fluid for Japan: A randomized non-inferiority clinical trial of safety and efficacy

Submission date
02/02/2016

Recruitment status
No longer recruiting

Registration date
08/03/2016

Overall study status
Completed

Last Edited
25/04/2023

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) is a long-term condition where the kidneys do not work properly. In a healthy person, the kidneys are responsible for filtering out the waste products and excess water in the blood, and converting them into urine. In patients suffering from CKD, the kidneys are unable to do this, and so the body is unable to get rid of the waste products building up in the blood. There are a number of treatments available which act to replace the function of the kidneys. One technique used is continuous ambulatory peritoneal dialysis (CAPD). This type of treatment is normally repeated between three and five times day, and is very popular as it can be done at home or work while the patient goes about their daily life. In this technique, the thin membrane (lining) that lines the peritoneal cavity (space in the abdomen that separates the organs from the abdominal wall) acts as a natural filter. It involves filling the abdominal cavity with a special fluid (dialysate) which is left to absorb waste products before being drained away. The dialysate used for CAPD contains different concentrations of sugars and salts and different amounts of waste are filtered out of the body depending on the concentrations used. It has been found that the concentrations of different mineral salts (particularly magnesium and calcium) in some dialysates can react in the body to produce high levels of bicarbonate in the blood. Biocarbonate is important for maintaining the pH of the blood (preventing it from becoming too acidic or alkaline) but if levels are too high (metabolic alkalosis) it can lead to dangerous consequences. A possible solution is a by using a double-chambered bag, such as with the product BLR350, which keeps bicarbonate separate from calcium and magnesium in order to prevent the creation of more bicarbonate. The aim of this study is to test the safety of using BLR350 for CAPD and to find out if it can prevent metabolic alkalosis.

Who can participate?
CKD patients over 20 years old who have been treated using CAPD for at least 3 months.

What does the study involve?
Participants are randomly allocated to one of two groups. For those in group one, each time the CAPD procedure is done, 2L of BLR350 is used as the dialysate fluid. For group two, each time the CAPD procedure is done, 2L of Dianeal PD-2 (normal dialysate solution) is used as the

dialysate fluid. Participants in both groups use their assigned dialysate every time they dialyse for 8 weeks. At the start of the study, and then again after 4, 8 and 12 weeks, participants have a blood test in order to measure how well the dialysis is working at replacing kidney function, and to have the amounts of bicarbonates and different minerals in the blood measured.

What are the possible benefits and risks of participating?
Participants may benefit from a lower blood bicarbonate level. There are no risks for participants taking part in the study as the techniques used in the study are treatments that are already offered in standard practice, although some participants may experience pain or bruising when having blood taken.

Where is the study run from?
24 hospitals in Japan.

When is the study starting and how long is it expected to run for?
November 2002 to April 2004

Who is funding the study?
Baxter Limited (Japan)

Who is the main contact?
Mr Shohi Saraya

Contact information

Type(s)
Public

Contact name
Mr Shoji Saraya

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Toranomon Hills Mori Tower 20F
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105-6320

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BLR350-01

Study information

Scientific Title
A randomized parallel-group comparative study to verify efficacy (non-inferiority) of BLR350 using Dianeal PD-2 as a comparator in patients with chronic renal failure receiving CAPD (Continuous Ambulatory Peritoneal Dialysis)

Study objectives
To verify the efficacy (non-inferiority) and safety of BLR350 using Dianeal PD-2 as a comparator in patients with chronic renal failure receiving CAPD therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board, Baxter Limited (Japan), 23/07/2002

Study design
Prospective randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

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
Chronic renal failure

Interventions
Participants fulfilling the eligibility are randomly allocated into one of two arms.

Active treatment arm: Each participant is given BLR350 to use as their peritoneal dialysate for a total of 8 weeks. The process is repeated between 3 and 5 times every day as required, using a total of 2L dialysate at each exchange.

Control treatment arm: Each participant is given Dianeal PD-2 to use as their peritoneal dialysate for a total of 8 weeks. The process is repeated between 3 and 5 times every day as required, using a total of 2L dialysate at each exchange.

All participants are followed up at 4 weeks.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
1. BLR350 2. Dianeal PD-2

Primary outcome measure
Peritoneal creatinine clearance and ultrafiltration volume are measured using blood and dialysis effluent analysis at baseline, 4, 8 and 12 weeks.

Secondary outcome measures
1. Peritoasuneal urea clearance is measured using blood and dialysis effluent analysis at baseline, 4, 8 and 12 weeks
2. Electrolyte (Na, K, Cl, Ca, Mg, P) concentration is measured using blood analysis at baseline, 4, 8 and 12 weeks
3. Plasma bicarbonate concentration is measured using blood analysis at baseline, 4, 8 and 12 weeks

Overall study start date
06/11/2002

Completion date
15/04/2004

Eligibility

Key inclusion criteria
1. Patients that have been continuously undergoing CAPD therapy for at least 3 months before the start of the baseline period
2. Patients that have been continuously using solely 2 L of Dianeal PD-2 for at least 4 weeks before the start of the baseline period
3. Patients that have given written consent to participate in this study
4. Patients that are aged over20 years at the time of giving consent
5. Either male or female patients may be enrolled, and either inpatients or outpatients may be enrolled

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
53 patients in Arm 1 and 58 patients in arm 2 were enrolled.

Total final enrolment
113

Key exclusion criteria
1. Patients that have a tunnel infection or a severe exit-site infection and are likely to develop peritonitis
2. Patients that have developed peritonitis or have not recovered from peritonitis within 4 weeks before the start of the baseline period
3. Patients with a serious disease other than chronic renal failure (e.g., malignant tumor, hepatic cirrhosis, active hepatitis, chronic heart failure, systemic infection, significant malnutrition, significant peritoneal membrane dysfunction, negative ultrafiltration and likely to convert to hemodialysis)
4. Patients that have participated in another clinical study within 6 months before obtaining consent
5. Patients that are pregnant, lactating or may be pregnant
6. In addition, patients that have been judged to be ineligible to participate in this study by the investigator/sub-investigator

Date of first enrolment
06/11/2002

Date of final enrolment
26/12/2003

Locations

Countries of recruitment
Japan

Study participating centre
Obihiro-Kosei General Hospital
Japan
080-0016

Study participating centre
Caress Alliance Nikko-Kinen Hospital
Japan
051-8501

Study participating centre
Yamagata University School of Medical Hospital
Japan
990-9585

Study participating centre
Toride Kyodo General Hospital
Japan
302-0022

Study participating centre
Kameda Medical Center
Japan
296-8602

Study participating centre
Saitama Medical University Hospital
Japan
350-0495

Study participating centre
Saitama Medical University Medical Center
Japan
350-8550

Study participating centre
Tokyo Medical University Hospital
Japan
160-0023

Study participating centre
Tokyo Jikeikai University Hospital
Japan
105-8471

Study participating centre
Tokyo Women’s Medical University Hospital
Japan
162-8666

Study participating centre
Juntendo University School of Medical Hospital
Japan
113-8431

Study participating centre
Tokyo Women’s Medical University Second Hospital
Japan
116-8567

Study participating centre
Toranomon Hospital
Japan
105-8470

Study participating centre
Yokosuka Kyosai Hospital
Japan
238-8558

Study participating centre
Shonan Kamakura General Hospital
Japan
247-8533

Study participating centre
Fujita Health University Hospital
Japan
470-1192

Study participating centre
Nara Medical University Hospital
Japan
634-8522

Study participating centre

Okayama Saiseikai General Hospital
Japan
700-8511

Study participating centre
Kurashiki Central Hospital
Japan
710-8602

Study participating centre
Akane-kai Tschiya General Hospital
Japan
730-8655

Study participating centre
Takamatsu Red Cross Hospital
Japan
760-0017

Study participating centre
Kumamoto Central Hospital
Japan
862-0965

Study participating centre
Saiseikai Kumamoto Hospital
Japan
861-4193

Study participating centre
Toranomon Hospital Annex
Japan
213-8587

Study participating centre

Nankai Hospital
Japan
876-0857

Study participating centre
St. Luke’s International Hospital
Japan
104-8560

Study participating centre
Tokyo Saiseikai Central Hospital
Japan
108-0073

Study participating centre
Gifu Prefectural General Medical Center
Japan
500-8717

Study participating centre
Hiroshima University Hospital
Japan
734-8551

Sponsor information

Organisation
Baxter Limited

Sponsor details
Toranomon Hills Mori Tower 20F
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Sponsor type
Industry

Website
http://www.baxter.co.jp

ROR
https://ror.org/02d6ew870

Funder(s)

Funder type
Not defined

Funder Name
Baxter Limited

Results and Publications

Publication and dissemination plan
Planned publication in Clinical and Experimental Nephrology.

Intention to publish date
31/07/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/10/2016	25/04/2023	Yes	No