

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	<input type="checkbox"/> Prospectively registered
Registration date 08/03/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/04/2023	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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. Bicarbonate 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

Contact details

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Japan

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 over 20 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 Tschia 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
1-23-1, Toranomon, Minato-ku,
Tokyo
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105-6320

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