

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

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
02/02/2016	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
08/03/2016	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
25/04/2023	Urological and Genital Diseases	

## 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 Shoji Saraya

## Contact information

**Type(s)**

Public

**Contact name**

Mr Shoji Saraya

**Contact details**

Toranomon Hills Mori Tower 20F

1-23-1, Toranomon, Minato-ku,

Tokyo

Japan

105-6320

## Additional identifiers

**Protocol serial number**

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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

**ROR**

<https://ror.org/02d6ew870>

## **Funder(s)**

**Funder type**

Not defined

**Funder Name**

Baxter Limited

## **Results and Publications**

**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?
<a href="#">Results article</a>		25/10/2016	25/04/2023	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes