

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 BLR250 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 BLR250 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 BLR250 is used as the dialysate fluid. For group two, each time the CAPD procedure is done, 2L of Dianeal PD-4 (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?

March 2003 to March 2004

Who is funding the study?

Baxter Limited (Japan)

Who is the main contact?

Mr Shohi Saraya

Contact information

Type(s)

Scientific

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

BLR250-01

Study information

Scientific Title

A randomized parallel-group comparative study to verify efficacy (non-inferiority) of BLR250 using Dianeal PD-4 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 BLR250 using Dianeal PD-4 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

Primary study design

Interventional

Study design

Prospective randomized parallel trial

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 BLR250 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-4 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. BLR250 2. Dianeal PD-4

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

18/03/2004

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-4 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

108

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. Patients that have been judged to be ineligible to participate in this study by the investigator /sub-investigator

Date of first enrolment

24/03/2003

Date of final enrolment

28/11/2003

Locations**Countries of recruitment**

Japan

Study participating centre

Asahikawa Red Cross Hospital

Japan

070-8530

Study participating centre

Sendai Social Insurance Hospital

Japan

981-8501

Study participating centre

Tokyo Jikei-kai Medical School Hospital

Japan

105-8471

Study participating centre

Tokyo Jikei-kai Medical School Kashiwa Hospital

Japan

277-8567

Study participating centre

Mitsui Memorial Hospital

Japan

101-8643

Study participating centre

Nihon University Itabashi Hospital

Japan
173-8610

Study participating centre

St. Marianna University School of Medicine Hospital

Japan
216-8511

Study participating centre

Hospital Affiliating with Kanagawa Prefecture Nursing School

Japan
235-0022

Study participating centre

Showa University Fujigaoka Hospita

Japan
227-8501

Study participating centre

Aichi Medical University Hospital

Japan
480-1195

Study participating centre

Chukyo Hospita

Japan
457-8510

Study participating centre

Clinic affiliating with Inoue Hospital

Japan
564-0053

Study participating centre

Kinki University School of Medicine Hospital

Japan
589-8511

**Study participating centre
Osaka Koseinenkin Hospital**

Japan
553-0003

**Study participating centre
Hiroshima University Hospital**

Japan
734-8551

**Study participating centre
Tokushima Red Cross Hospital**

Japan
773-8502

**Study participating centre
Saiseikai Yahata General Hospital**

Japan
805-0050

**Study participating centre
Shizuoka General Hospital**

Japan
420-8527

**Study participating centre
Shirasagi Clinic**

Japan
546-0002

Study participating centre

Osaka City University School of Medicine Hospital

Japan

545-8586

Study participating centre

Teine Keijinkai Hospital

Japan

006-8555

Study participating centre

Tokai University School of Medicine Hospital

Japan

259-1193

Study participating centre

Tokuyama Central Hospital

Japan

745-8522

Study participating centre

Hakodate Goryoukaku Hospital

Japan

040-8611

Study participating centre

Kawasaki Medical School Hospital

Japan

701-0192

Study participating centre

Saiseikai Central Hospital

Japan

108-0073

Study participating centre

Tokyo Kyosai Hospital

Japan

153-8934

Study participating centre

Kumamoto Central Hospital

Japan

862-0965

Sponsor information

Organisation

Baxter Limited

ROR

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

Funder(s)

Funder type

Industry

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?
Results article		25/10/2016	25/04/2023	Yes	No