ClinicalTrials.gov PRS
Protocol Registration and Results System

Protocol Registration and Results Preview

This is a rough approximation of how the Protocol Registration and Results will appear on the ClinicalTrials.gov public web site.

IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients (Impendia)

ClinicalTrials.gov Identifier: NCT00567489

Recruitment Status: Completed
First Posted: *
Last Update Posted: *

* Date not available in PRS

Sponsor:

Baxter Healthcare Corporation

Information provided by (Responsible Party):

Baxter Healthcare Corporation

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

Study Description

Brief Summary:

Primary Objective: To demonstrate that use of glucose sparing prescriptions (PEN vs Dianeal only) in diabetic (Type 1 and Type 2) Continuous Ambulatory Peritoneal Dialysis (CAPD) and Automated Peritoneal Dialysis (APD)patients leads to improved metabolic control as measured by the magnitude of change from the baseline value in the HbA1c levels.

Secondary Objectives: To demonstrate that use of glucose-sparing PD solutions (PEN vs Dianeal only) in diabetic (Type 1 and Type 2) CAPD and APD patients leads to lower glycemic-control medication requirements, decreased incidence of severe hypoglycemic events requiring medical intervention, improved metabolic control, nutritional status, and Quality of Life. In a subgroup of patients, the impact of glucose-sparing PD solutions (PEN vs Dianeal only) on abdominal fat and left ventricular (LV) structure and function will be assessed.

Condition or disease	Intervention/treatment	Phase
ESRD Diabetes CAPD APD	Drug: Physioneal Drug: Dianeal Drug: Extraneal Drug: Nutrineal	Phase 4

Detailed Description:

The data represented in this module is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067). Given that the glucose content of the PD solutions is similar, the pooling of the results were considered a valid method to answer the underlying research questions.

Study Design

Study Type:	Interventional
Actual Enrollment:	137 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control in Diabetic CAPD and APD Patients

Multi-Center, Prospective, Randomized Trial To Demonstrate Improved Metabolic Control of PEN VS Dianeal Only in Diabetic CAPD and APD Patients - The Impendia Trial NCT00567489

Study Start Date:	January 2008
Actual Primary Completion Date:	July 2011
Actual Study Completion Date:	July 2011

Arms and Interventions

Arm	Intervention/treatment
Active Comparator: Non glucose sparing Dianeal only	Drug: Dianeal Dianeal 1.5% Dextrose (1.30% glucose), 2.5% Dextrose (2.27% glucose), 4.5% Dextrose (3.86% glucose)
Experimental: glucose sparing PEN solutions: Nutrineal, Extraneal, and Physioneal	Drug: Physioneal Physioneal 40 or Physioneal 35 Drug: Extraneal 7.5% Icodextrin Drug: Nutrineal Amino Acids 1.1%

Outcome Measures

Primary Outcome Measure:

1. Change From the Baseline Value in HbA1c at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
   HbA1c is a specific glycohemoglobin, and adduct of glucose attached to the beta-chain terminal valine residue. Measured using a Tina-quant immunological assay suitable for samples from end stage renal disease (ESRD) patients and with icodextrin metabolites or equivalent. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

Secondary Outcome Measures:

1. Change From Baseline in Glycemic Control Medication Usage at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
   This data used diabetic prescription drug information from insulin and oral glycemic control concomitant medications reported. Glycemic control medications classes allowed were limited to insulin, sulfonylureas, and thiazolidinediones. Subjects were provided with a paper diary on which they recorded doses of all glycemic control medications taken for 1 day prior to the Screening visit and for 8 days prior to the study visits at Month 3 and Month 6. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

2. Number of Severe Hypoglycemic Event Requiring Medical Intervention [Time Frame: Baseline through Month 6 (End of Study)]
   Severe hypoglycemia is defined by DCCT (Diabetes Control and Complications Trial) as any episode requiring external assistance to aid recovery or resulted in seizures or coma and included, as part of the definition, that the subject's blood glucose concentration had to have been documented as < 50mg/dL (<2.8mmol/L) for hypoglycemia, and/or the clinical manifestations had to have been reversed with oral carbohydrate, intramuscular glucagon, or intravenous glucose. Descriptive statistics were done, no inferential statistical analyses were performed.

3. Change From Baseline of Metabolic Control Determined by Lipid Profile and Triglycerides at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
   Values for Total Cholesterol (TC), Low Density Lipoprotein Cholesterol (LDLC), High Density Lipoprotein Cholesterol (HDLC), Very Low Density Lipoprotein (VLDL), and Triglycerides are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

4. Change From Baseline of Metabolic Control Determined by Lipoproteins at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
   Values for Lipoprotein A (Lp(a)), Apolipoprotein A1 (Apo A1), and Apolipoprotein B (Apo B) are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

5. Change From Baseline of Metabolic Control Determined by Insulin Action of Insulin and C-peptide at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
   Values for Insulin and C-peptide are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

6. Change From Baseline of Metabolic Control Determined by Insulin Action of Pro-Insulin at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
   Values for Pro-Insulin are provided. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

7. Number of Participants by Change From Baseline Score in Subjective Global Assessment (SGA) Class at Month 6 [Time Frame: Baseline and Month 6 (End of Study)]
   Nutritional Status by SGA include the following: (a) Weight change over 6 months, (b) dietary history of food intake over the previous 24-hour period with a determination by the subject as to whether this was a typical or atypical diet for the subject, (c) significant and sustained gastrointestinal distress, (d) functional status, (e) metabolic stress including frequent infections, fever, peritonitis, uncontrolled diabetes and active inflammatory bowel disease. The SGA used a 7-point scale, where a decrease score in the change from baseline shows signs of increased malnourishment, and an increased score (e.g., +2) is improved nourishment. Scale: 6 - 7 = very mild risk to well-nourished; 3 - 5 = no clear sign of normal status or severe malnutrition; 1 - 2 = severely malnourished

8. Change From Baseline of Nutritional Status Determined by Albumin and Total Protein (Labs) at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
   Values for Albumin and Total Protein are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

9. Change From Baseline of Nutritional Status Determined by PNA and nPNA (Labs) at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
   Values for Protein Nitrogen Appearance (PNA) and normalized protein nitrogen appearance (nPRNA) are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

10. Change From Baseline of Nutritional Status Determined by Pre-albumin (Labs) at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
    Values for Pre-albumin are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

11. Change From Baseline of Nutritional Status Determined by Drained Body Weight at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
    Values for Drained Body Weight are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

12. Change From Baseline of Nutritional Status Determined by Body Mass Index (BMI) at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
    Values for BMI are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

13. Change From Baseline of Nutritional Status Determined by Waist Circumference at Month 6 [Time Frame: Baseline, Month 6 (End of Study)]
    Values for Waist Circumference are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

14. Change From Baseline of Nutritional Status Determined by Protein and Calories at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
    Values for Protein and Calories are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

15. Change From Baseline in QOL Based on the EQ 5D Questionnaire Index at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
    European Quality of Life, 5 Dimensions (EQ-5D) generates a single index score based on a descriptive system that defines health in terms of 5 dimensions, consisting of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The possible range for each dimension is 1 to 3, where 1=no problems, 2=moderate problems, 3=extreme problems. Higher score implies more problems (worsening). According to this classification, 243 potential health states are defined. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

16. Change From Baseline in QOL Based on the EQ 5D Quest Health Status at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
    Visual analogue scale to generate a self-perceived rating of health status. Visual analogue scale is the second part of the questionnaire, asking to mark health status on the day of the interview on a 20 cm vertical scale with end points of 0 and 100. There are notes at the both ends of the scale that the bottom rate (0) corresponds to " the worst health you can imagine", and the highest rate (100) corresponds to "the best health you can imagine". Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

17. Change From Baseline in QOL Based on the Diabetes Symptom Checklist (DSC) at Month 3 and 6 [Time Frame: Baseline, Month 3, Month 6 (End of Study)]
    The Diabetes Symptoms Checklist was designed to assess the presence and perceived burden of diabetes-related symptoms. Respondents were to consider

troublesomeness of 34 symptoms on a 5-point scale ranging from 5="extremely" to 1="not at all." For symptoms/side-effects not experienced, the item was scored as 0. Symptoms were grouped into the following subscales: psychological fatigue, psychological cognitive, neurology pain, neurology sensory, cardiology, ophthalmology, hypoglycemia, hyperglycemia. Subscale scores were calculated as the sum of the given subscale divided by the total number of items in the scale. Total score was computed from the sum of the 8 subscales and ranged from 0 to 40. Higher scores indicate greater symptom burden. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

18. Change From Baseline of MRI Body Composition at Month 6 [Time Frame: Baseline, Month 6 (End of Study)]
    Values for Abdominal Subcutaneous Fat Volume and Abdominal Visceral Fat Volume are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

19. Change From Baseline of Left Ventricular (LV) End Diastolic and Systolic Volume as Determined by MRI at Month 6 [Time Frame: Baseline, Month 6 (End of Study)]
    Values for Left Ventricular (LV) End Diastolic and Systolic Volume are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

20. Change From Baseline of Left Ventricular (LV) Mass Without and With Pap Muscles as Determined by MRI at Month 6 [Time Frame: Baseline, Month 6 (End of Study)]
    Values for Left Ventricular (LV) Mass Without and With Pap Muscles are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

21. Change From Baseline of Left Ventricular (LV) Ejection Fraction as Determined by MRI at Month 6 [Time Frame: Baseline, Month 6 (End of Study)]
    Values for Left Ventricular (LV) Ejection Fraction are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

Eligibility Criteria

Ages Eligible for Study: 18 Years and older

Sexes Eligible for Study: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. M/F patients 18 years of age or older
2. Diagnosis of ESRD (GFR ≤ 15 mL/min)
3. CAPD or APD using only Dianealand/or Physioneal, at least 1 exchange of 2.5% or 4.25% dextrose/day, no prescribed dry time
4. DM (Type 1 and 2) on glycemic-control medication, for 90 days
5. HbA1c > 6.0% but ≤ 12.0%
6. Blood hemoglobin ≥ 8.0 g/dL, but ≤ 13.0 g/dL

Exclusion Criteria:

1. Cardiovascular event within the last 90 days
2. Ongoing clinically significant congestive heart failure (NYHA class III or IV)
3. Allergy to starch-based polymers
4. Glycogen storage disease
5. Maltose, or isomaltose intolerance
6. Peritonitis, exit-site or tunnel infection treated with antibiotics within last 30 days
7. Mean Arterial Pressure (MAP) ≥ 125 mm Hg, or volume depleted (MAP < 77) at Screening.
8. Serum urea > 30 mmol/L
9. Exposure to Extraneal or Nutrineal within the last 60 days prior to Screening visit, Day 1.
10. Receiving rosiglitazone maleate

Contacts and Locations

Locations

Hong Kong

Kwong Wah Hospital
Kowloon, Hong Kong

Prince of Wales Hospital Chinese University of Hong Kong
Sha Tin, N.T., Hong Kong

Alice Ho Miu Ling Nethersole Hospital
Tai Po, N.T., Hong Kong

Russia

Moscow Clinical Hospital # 52
Moscow, Russia

Moscow Hospital n a S P Botkin
Moscow, Russia

Moscow Research n a M F Vladimirsky

Moscow, Russia
Moscow State Medical Institution: "Municipal Clinical Hospital #7 "
Moscow, Russia
Samara Hospital n a M I Kalinin
Samara, Russia
St Petersburg St Elizabeth Hospital
St Petersburg, Russia
St Petersburg Mariinskaya Hospital
St Petersburg, Russia

Singapore

National University Hospital
Singapore, Singapore, 119074
Tan Tock Seng Hospital
Singapore, Singapore, 308433
Singapore General Hospital
Singapore, Singapore, 169608

South Korea

Yonsei University of Medical Center Severance Hospital
Seoul, South Korea, 120-752
Seoul National University Hospital
Seoul, South Korea, 110-744
Kyungpook National University Hospital
Chung-Gu, Deagu, South Korea, 700-721
Daegu Fatima Hospital
Dong-gu, Deagu, South Korea, 701-600
Yeungnam University Medical Center
Nam-gu, Deagu, South Korea, 705-717

Taiwan

China Medical University Hospital
Taichung, Taiwan, 404
National Taiwan University Hospital
Taipei, Taiwan, 100

Investigators

Study Director:	Baxter Healthcare Corporation	Call central contact for information

More Information

Publications:

Oreopoulos DG. Peritoneal dialysis beyond the year 2000. Perit Dial Int. 1999;19 Suppl 3:S35-42; discussion S43.

Delarue J, Maingourd C, Couet C, Vidal S, Bagros P, Lamisse F. Effects of oral glucose on intermediary metabolism in continuous ambulatory peritoneal dialysis patients versus healthy subjects. Perit Dial Int. 1998 Sep-Oct;18(5):505-11.

Holmes CJ, Shockley TR. Strategies to reduce glucose exposure in peritoneal dialysis patients. Perit Dial Int. 2000;20 Suppl 2:S37-41. Review.

Furuya R, Odamaki M, Kumagai H, Hishida A. Beneficial effects of icodextrin on plasma level of adipocytokines in peritoneal dialysis patients. Nephrol Dial Transplant. 2006 Feb;21(2):494-8. Epub 2005 Oct 12.

American Diabetes Association. Standards of medical care for patients with diabetes mellitus. Diabetes Care. 2003 Jan;26 Suppl 1:S33-50. Erratum in: Diabetes Care. 2003 Mar;26(3):972.

Martikainen T, Teppo AM, Gronhagen-Riska C, Ekstrand A. Benefit of glucose-free dialysis solutions on glucose and lipid metabolism in peritoneal dialysis patients. Blood Purif. 2005;23(4):303-10. Epub 2005 Jun 23.

Responsible Party:	Baxter Healthcare Corporation
ClinicalTrials.gov Identifier:	NCT00567489
Other Study ID Numbers:	31998
Last Verified:	August 2018

Human Subjects Protection Review Board Status: Approved

Study Results

Participant Flow

Recruitment Details	The data represented in this module is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067). Given that the glucose content of the PD solutions is similar, the pooling of the results were considered a valid method to answer the underlying research questions.
Pre-assignment Details	

Arm/Group Title			Total

	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions	Total (Not public)
▼ Arm/Group Description	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.	
Period Title: **Overall Study**			
Started	127	124	251
Completed	120	101	221
Not Completed	7	23	30
Reason Not Completed			
Adverse Event	6	14	20
Physician Decision	0	4	4
Withdrawal by Subject	0	2	2
Renal Transplantation	0	3	3
Unknown	1	0	1
(Not Public)	Not Completed =7 Total from all reasons =7	Not Completed =23 Total from all reasons =23	

Baseline Characteristics

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions	Total
▼ Arm/Group Description	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.	
Overall Number of Baseline Participants	127	124	**251**
▼ Baseline Analysis Population Description	The data represented in this module is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202),		

NCT01219959 (protocol ID 51067). Given that the glucose content of the PD solutions is similar, the pooling of the results were considered a valid method to answer the underlying research questions.

Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	127 participants	124 participants	251 participants
		58 (12.8)	57.3 (12)	57.65 (12.4)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	127 participants	124 participants	251 participants
	Female	59 46.46%	64 51.61%	123 49%
	Male	68 53.54%	60 48.39%	128 51%
Race/Ethnicity, Customized Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	127 participants	124 participants	251 participants
Baseline	Asian	41 32.28%	42 33.87%	83 33.07%
	Black	1 0.79%	0 0%	1 0.4%
	Caucasian	41 32.28%	41 33.06%	82 32.67%
	Hispanic	32 25.2%	31 25%	63 25.1%
	Other	12 9.45%	10 8.06%	22 8.76%

Outcome Measures

1. Primary Outcome

Title:	Change From the Baseline Value in HbA1c at Month 3 and 6
Description:	HbA1c is a specific glycohemoglobin, and adduct of glucose attached to the beta-chain terminal valine residue. Measured using a Tina-quant immunological assay suitable for samples from end stage renal disease (ESRD) patients and with icodextrin metabolites or equivalent. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.

ID: 31998 IMPENDIA-PEN VS Dianeal Only Improved Metabolic Control in Diabetic CAPD and APD Patients NCT00567489

Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Primary Efficacy Intent-to-Treat (ITT) population included all subjects randomized with a minimum of a baseline HbA1c value determined and one PD exchange using study solution performed. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489, NCT00567398, NCT01219959.

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	125	119
Mean (Standard Deviation) Unit of Measure: Percent Change		
Row Title		
Month 3	0.2 (1.1)	-0.6 (1.3)
Month 6	0 (1.2)	-0.6 (1.5)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	ANOVA

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.6
	Confidence Interval	(2-Sided) 95% 0.2 to 0.9
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.006
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.5
	Confidence Interval	(2-Sided) 95% 0.1 to 0.8
	Estimation Comments	[Not specified]

2. Secondary Outcome

Title:	Change From Baseline in Glycemic Control Medication Usage at Month 3 and 6
▼ Description:	This data used diabetic prescription drug information from insulin and oral glycemic control concomitant medications reported. Glycemic control medications classes allowed were limited to insulin, sulfonylureas, and thiazolidinediones. Subjects

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

	were provided with a paper diary on which they recorded doses of all glycemic control medications taken for 1 day prior to the Screening visit and for 8 days prior to the study visits at Month 3 and Month 6. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Analysis used data from prescription information of concomitant medications reported. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	126	124
Mean (Standard Deviation) Unit of Measure: Percent Change		
Row Title		
Insulin: Month 3	3.5 (21.2)	-3.3 (16.4)
Insulin: Month 6	2.9 (25.4)	-3.8 (23.9)
Oral hypoglycemic: Month 3	1.3 (12.6)	5 (51.3)
Oral hypoglycemic: Month 6	-0.5 (12.7)	6.4 (52.3)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Insulin-Month 3

	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.312
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	5
	Confidence Interval	(2-Sided) 95% -4.7 to 14.7
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Insulin-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.342
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	4.7
	Confidence Interval	(2-Sided) 95% -5.0 to 14.4

	Estimation Comments	[Not specified]

3. Secondary Outcome

Title:	Number of Severe Hypoglycemic Event Requiring Medical Intervention
▼ Description:	Severe hypoglycemia is defined by DCCT (Diabetes Control and Complications Trial) as any episode requiring external assistance to aid recovery or resulted in seizures or coma and included, as part of the definition, that the subject's blood glucose concentration had to have been documented as < 50mg/dL (<2.8mmol/L) for hypoglycemia, and/or the clinical manifestations had to have been reversed with oral carbohydrate, intramuscular glucagon, or intravenous glucose. Descriptive statistics were done, no inferential statistical analyses were performed.
Time Frame:	Baseline through Month 6 (End of Study)

▼ Outcome Measure Data

▼ Analysis Population Description

Intent-to-Treat (ITT) population included all subjects randomized with a minimum of a baseline HbA1c value determined and one PD exchange using study solution performed. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	127	124
Measure Type: Number Unit of Measure: events	1	3

4. Secondary Outcome

Title:	Change From Baseline of Metabolic Control Determined by Lipid Profile and Triglycerides at Month 3 and 6
▼ Description:	

	Values for Total Cholesterol (TC), Low Density Lipoprotein Cholesterol (LDLC), High Density Lipoprotein Cholesterol (HDLC), Very Low Density Lipoprotein (VLDL), and Triglycerides are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data

▼ Analysis Population Description

ITT population used. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	127	124
Mean (Standard Deviation) Unit of Measure: mmol/L		
Row Title		
Cholesterol: Month 3 (n=127, 124)	0.1 (1.1)	-0.5 (1.2)
Cholesterol: Month 6 (n=127, 124)	0 (1.2)	-0.4 (1.2)
LDLC: Month 3 (n=127, 124)	0.1 (1.0)	-0.2 (1.1)
LDLC: Month 6 (n=127, 124)	0.1 (1.1)	-0.1 (1.2)
HDLC: Month 3 (n=127, 124)	0 (0.2)	0 (0.3)
HDLC: Month 6 (n=127, 124)	0 (0.3)	0 (0.3)
VLDL: Month 3 (n=126, 124)	-0.1 (0.9)	-0.3 (0.8)
VLDL: Month 6 (n=126, 124)	-0.1 (0.8)	-0.3 (0.9)

Triglycerides: Month 3 (n=127, 124)	-0.1 (1.9)	-0.7 (1.8)
Triglycerides: Month 6 (n=127, 124)	-0.3 (1.9)	-0.6 (1.9)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Cholesterol-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.010
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.5
	Confidence Interval	(2-Sided) 95% 0.1 to 0.9
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Cholesterol-Month 6

	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.073
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Median Difference (Final Values)
	Estimated Value	0.3
	Confidence Interval	(2-Sided) 95% 0 to 0.7
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for LDLC-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.181
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)

	Estimated Value	0.2
	Confidence Interval	(2-Sided) 95% -0.1 to 0.5
	Estimation Comments	[Not specified]

▼ Statistical Analysis 4 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for LDLC-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.593
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.1
	Confidence Interval	(2-Sided) 95% -0.2 to 0.4
	Estimation Comments	[Not specified]

▼ Statistical Analysis 5 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment

		Groups for HDLC-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.198
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.1
	Confidence Interval	(2-Sided) 95% -0.2 to 0
	Estimation Comments	[Not specified]

▼ Statistical Analysis 6 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for HDLC-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.298
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
	Estimation Parameter	

Method of Estimation		Mean Difference (Final Values)
	Estimated Value	0
	Confidence Interval	(2-Sided) 95% -0.1 to 0
	Estimation Comments	[Not specified]

▼ Statistical Analysis 7 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for VLDL-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.4
	Confidence Interval	(2-Sided) 95% 0.2 to 0.6
	Estimation Comments	[Not specified]

▼ Statistical Analysis 8 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	

		Estimate of Least Square Means Comparing Treatment Groups for VLDL-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.003
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.3
	Confidence Interval	(2-Sided) 95% 0.1 to 0.5
	Estimation Comments	[Not specified]

▼ Statistical Analysis 9 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Triglycerides-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	ANOVA

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.8
	Confidence Interval	(2-Sided) 95% 0.4 to 1.3
	Estimation Comments	[Not specified]

▼ Statistical Analysis 10 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Triglycerides-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.002
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.7
	Confidence Interval	(2-Sided) 95% 0.3 to 1.1
	Estimation Comments	[Not specified]

5. Secondary Outcome

Title:	Change From Baseline of Metabolic Control Determined by Lipoproteins at Month 3 and 6

▼ Description:	Values for Lipoprotein A (Lp(a)), Apolipoprotein A-1 (Apo A1), and Apolipoprotein B (Apo B) are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Subset of ITT population that had evaluable data. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	119	120
Mean (Standard Deviation) Unit of Measure: mg/dL		
Row Title		
Lp(a): Month 3 (n=118,120)	2.3 (8.9)	3.3 (9.8)
Lp(a): Month 6 (n=118,120)	6.7 (15.4)	6.8 (18)
Apo A1: Month 3 (n=119,120)	-2.1 (16.4)	-9.3 (17.5)
Apo A1: Month 6 (n=119,120)	-3.8 (17.7)	-10.5 (18.4)
Apo B: Month 3 (n=119,120)	5.3 (24.2)	-8.5 (18.4)
Apo B: Month 6 (n=119,120)	5.2 (25.4)	-3.6 (23.9)

▼ Statistical Analysis 1 ✔

	Comparison Group Selection	

Statistical Analysis Overview		Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Lp(a)-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.485
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-2.3
	Confidence Interval	(2-Sided) 95% -8.6 to 4.1
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Lp(a)-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
	P-Value	0.556

Statistical Test of Hypothesis	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.9
	Confidence Interval	(2-Sided) 95% -8.2 to 4.4
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Apo A1-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.101
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	5.6
	Confidence Interval	(2-Sided) 95% -1.1 to 12.2
	Estimation Comments	[Not specified]

▼ Statistical Analysis 4 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Apo A1-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.134
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	5
	Confidence Interval	(2-Sided) 95% -1.5 to 11.5
	Estimation Comments	[Not specified]

▼ Statistical Analysis 5 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Apo B-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]

	P-Value	0.004

Statistical Test of Hypothesis	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	11.4
	Confidence Interval	(2-Sided) 95% 3.6 to 19.2
	Estimation Comments	[Not specified]

▼ Statistical Analysis 6 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Apo B-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.030
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	8.4
	Confidence Interval	(2-Sided) 95% 0.8 to 15.9
	Estimation Comments	[Not specified]

6. Secondary Outcome

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control in Diabetic CAPD and APD Patients NCT00567489

Title:	Change From Baseline of Metabolic Control Determined by Insulin Action of Insulin and C-peptide at Month 3 and 6
▼ Description:	Values for Insulin and C-peptide are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Evaluable subset of ITT population that had blood draw at baseline for these lab parameters were used. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	119	120
Mean (Standard Deviation) Unit of Measure: pg/mL		
Row Title		
Insulin: Month 3	70.3 (514.2)	69.4 (809.4)
Insulin: Month 6	146.3 (616)	96.6 (1301.9)
C-peptide: Month 3	340.8 (2393.7)	70.5 (2687.2)
C-peptide: Month 6	388.3 (2660.5)	504.1 (2462.5)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Insulin-Month 3

	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.655
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-56.5
	Confidence Interval	(2-Sided) 95% -304.6 to 191.7
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Insulin-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.811
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-29.2

	Confidence Interval	(2-Sided) 95% -268.9 to 210.5
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for C-Peptide-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.419
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	441.3
	Confidence Interval	(2-Sided) 95% -630.4 to 1513.1
	Estimation Comments	[Not specified]

▼ Statistical Analysis 4

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for C-Peptide-Month 6

	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.820
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	121.8
	Confidence Interval	(2-Sided) 95% -927.9 to 1171.5
	Estimation Comments	[Not specified]

7. Secondary Outcome

Title:	Change From Baseline of Metabolic Control Determined by Insulin Action of Pro-Insulin at Month 3 and 6
▼ Description:	Values for Pro-Insulin are provided. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Evaluable subset of ITT population that had blood draw at baseline for these lab parameters were used. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

		(DLEN) used for 51067 study.
Overall Number of Participants Analyzed	119	120
Mean (Standard Deviation) Unit of Measure: pmol/L		
Row Title		
Pro-Insulin: Month 3	-1.8 (19.6)	13 (71.3)
Pro-Insulin: Month 6	3 (41.9)	0.4 (33.5)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Pro-Insulin-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.721
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-4.2
	Confidence Interval	(2-Sided) 95% -27.5 to 19
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions

	Comments	Estimate of Least Square Means Comparing Treatment Groups for Pro-Insulin-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.247
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	13.5
	Confidence Interval	(2-Sided) 95% -9.4 to 36.4
	Estimation Comments	[Not specified]

8. Secondary Outcome

Title:	Number of Participants by Change From Baseline Score in Subjective Global Assessment (SGA) Class at Month 6
▼ Description:	Nutritional Status by SGA include the following: (a) Weight change over 6 months, (b) dietary history of food intake over the previous 24-hour period with a determination by the subject as to whether this was a typical or atypical diet for the subject, (c) significant and sustained gastrointestinal distress, (d) functional status, (e) metabolic stress including frequent infections, fever, peritonitis, uncontrolled diabetes and active inflammatory bowel disease. The SGA used a 7-point scale, where a decrease score in the change from baseline shows signs of increased malnourishment, and an increased score (e.g., +2) is improved nourishment. Scale: 6 - 7 = very mild risk to well-nourished; 3 - 5 = no clear sign of normal status or severe malnutrition; 1 - 2 = severely malnourished If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Baseline and Month 6 (End of Study)

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Subset of ITT population that had evaluable data. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	120	104
Measure Type: Number Unit of Measure: participants		
Row Title		
+2 Score	1	2
+1 Score	19	24
0 Score	76	57
-1 Score	20	17
-2 Score	3	4
-3 Score	1	0

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimates of Ratio-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
	P-Value	0.624
	Comments	[Not specified]

Statistical Test of Hypothesis	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.89
	Confidence Interval	(2-Sided) 95% 0.55 to 1.43
	Estimation Comments	[Not specified]

9. Secondary Outcome

Title:	Change From Baseline of Nutritional Status Determined by Albumin and Total Protein (Labs) at Month 3 and 6
▼ Description:	Values for Albumin and Total Protein are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data

▼ Analysis Population Description

ITT population used. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	127	124
Mean (Standard Deviation) Unit of Measure: g/L		
Row Title		
Albumin: Month 3	-0.1 (3.1)	-0.6 (3.6)
Albumin: Month 6	0.5 (3)	-0.8 (3.9)

Total Protein: Month 3	0.1 (4.3)	0.2 (5.1)
Total Protein: Month 6	0.7 (4.9)	-0.9 (6.1)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Albumin-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.338
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.6
	Confidence Interval	(2-Sided) 95% -0.6 to 1.8
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Albumin-Month 6
		Superiority

	Type of Statistical Test	
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.029
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	1.3
	Confidence Interval	(2-Sided) 95% 0.1 to 2.5
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Total Protein-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.817
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.2

	Confidence Interval	(2-Sided) 95% -1.9 to 1.5
	Estimation Comments	[Not specified]

▼ Statistical Analysis 4 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Total Protein-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.091
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	1.4
	Confidence Interval	(2-Sided) 95% -0.2 to 2.9
	Estimation Comments	[Not specified]

10. Secondary Outcome

Title:	Change From Baseline of Nutritional Status Determined by PNA and nPNA (Labs) at Month 3 and 6
▼ Description:	Values for Protein Nitrogen Appearance (PNA) and normalized protein nitrogen appearance (nPRNA) are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

Outcome Measure Data

Analysis Population Description

Subset of ITT population that had evaluable data. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	79	79
Mean (Standard Deviation) Unit of Measure: g/kg/day		
Row Title		
PNA: Month 3	-0.8 (14.1)	12.8 (14.4)
PNA: Month 6	1 (18.6)	12.9 (17.5)
nPNA: Month 3	0 (0.2)	0.2 (0.2)
nPNA: Month 6	0 (0.3)	0.2 (0.3)

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for PNA-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.127
	Comments	[Not specified]

	Method	ANOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-10.2
	Confidence Interval	(2-Sided) 95% -23.3 to 2.9
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for PNA-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-10.3
	Confidence Interval	(2-Sided) 95% -16.4 to -4.3
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for nPNA-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.012
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.2
	Confidence Interval	(2-Sided) 95% -0.4 to -0.1
	Estimation Comments	[Not specified]

▼ Statistical Analysis 4 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for nPNA-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
	P-Value	<0.001

Statistical Test of Hypothesis	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.2
	Confidence Interval	(2-Sided) 95% -0.3 to -0.1
	Estimation Comments	[Not specified]

11. Secondary Outcome

Title:	Change From Baseline of Nutritional Status Determined by Pre-albumin (Labs) at Month 3 and 6
▼ Description:	Values for Pre-albumin are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data

▼ Analysis Population Description

Subset of ITT population that had evaluable data. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	83	85
Mean (Standard Deviation) Unit of Measure: mg/dL		
Row Title		

Month 3	0.4 (7.2)	1.9 (5.5)
Month 6	-1.0 (8.3)	-2.9 (5.9)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Pre-Albumin-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.019
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	3.2
	Confidence Interval	(2-Sided) 95% 0.5 to 5.8
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Pre-Albumin-Month 6
		Superiority

	Type of Statistical Test	
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.019
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	3
	Confidence Interval	(2-Sided) 95% 0.5 to 5.6
	Estimation Comments	[Not specified]

12. Secondary Outcome

Title:	Change From Baseline of Nutritional Status Determined by Drained Body Weight at Month 3 and 6
▼ Description:	Values for Drained Body Weight are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data

▼ Analysis Population Description

ITT population used. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

		(DLEN) used for 51067 study.
Overall Number of Participants Analyzed	127	124
Mean (Standard Deviation) Unit of Measure: kg		
Row Title		
Month 3	-0.2 (4.5)	-0.2 (3.5)
Month 6	0.2 (5.2)	-0.7 (3.3)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Drained Fat-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.884
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.3
	Confidence Interval	(2-Sided) 95% -3.9 to 3.4
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions

	Comments	Estimate of Least Square Means Comparing Treatment Groups for Drained Fat-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.716
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.7
	Confidence Interval	(2-Sided) 95% -3 to 4.3
	Estimation Comments	[Not specified]

13. Secondary Outcome

Title:	Change From Baseline of Nutritional Status Determined by Body Mass Index (BMI) at Month 3 and 6
▼ Description:	Values for BMI are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

ITT population used. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:		

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	127	124
Mean (Standard Deviation) Unit of Measure: kg/m2		
Row Title		
Month 3	-0.1 (1.5)	-0.1 (1.3)
Month 6	0.1 (1.9)	-0.3 (1.2)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for BMI-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.961
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0
	Confidence Interval	(2-Sided) 95% -1.2 to 1.1
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for BMI-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.581
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.3
	Confidence Interval	(2-Sided) 95% -0.8 to 1.5
	Estimation Comments	[Not specified]

14. Secondary Outcome

Title:	Change From Baseline of Nutritional Status Determined by Waist Circumference at Month 6
▼ Description:	Values for Waist Circumference are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Subset of ITT population that had evaluable data. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	123	122
Mean (Standard Deviation) Unit of Measure: cm	0 (6.4)	0.4 (5.9)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Waist Circumference-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.871
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.3
	Confidence Interval	(2-Sided) 95% -3.7 to 3.1
	Estimation Comments	[Not specified]

15. Secondary Outcome

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

Title:	Change From Baseline of Nutritional Status Determined by Protein and Calories at Month 3 and 6
▼ Description:	Values for Protein and Calories are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Subset of ITT population that had evaluable data. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	91	87
Mean (Standard Deviation) Unit of Measure: grams		
Row Title		
Protein: Month 3	-5.6 (14.1)	-4.9 (45.3)
Protein: Month 6	-0.1 (24.8)	4.5 (32.9)
Calories: Month 3	-76.8 (316.9)	-199.1 (525.1)
Calories: Month 6	30.9 (589.5)	108 (654)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Protein-Month 3

	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.608
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	5.2
	Confidence Interval	(2-Sided) 95% -14.7 to 25
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Protein-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.731
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.7

	Confidence Interval	(2-Sided) 95% -11.5 to 8.1
	Estimation Comments	[Not specified]

▼ Statistical Analysis 3 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Calories-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.377
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	185.3
	Confidence Interval	(2-Sided) 95% -227.5 to 598.1
	Estimation Comments	[Not specified]

▼ Statistical Analysis 4 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Calories-Month 6

	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.854
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-18.3
	Confidence Interval	(2-Sided) 95% -214.4 to 177.8
	Estimation Comments	[Not specified]

16. Secondary Outcome

Title:	Change From Baseline in QOL Based on the EQ 5D Questionnaire Index at Month 3 and 6
▼ Description:	European Quality of Life, 5 Dimensions (EQ-5D) generates a single index score based on a descriptive system that defines health in terms of 5 dimensions, consisting of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The possible range for each dimension is 1 to 3, where 1=no problems, 2=moderate problems, 3=extreme problems. Higher score implies more problems (worsening). According to this classification, 243 potential health states are defined. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0. If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data

▼ Analysis Population Description

ITT population used. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	127	124
Mean (Standard Deviation) Unit of Measure: Percent Change		
Row Title		
Month 3	-0.01 (0.18)	-0.04 (0.19)
Month 6	-0.04 (0.19)	-0.03 (0.17)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for EQ 5D Questionnaire Index-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.412
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.02
	Confidence Interval	(2-Sided) 95%

		-0.03 to 0.07
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for EQ 5D Questionnaire Index-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.485
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.02
	Confidence Interval	(2-Sided) 95% -0.07 to 0.03
	Estimation Comments	[Not specified]

17. Secondary Outcome

Title:	Change From Baseline in QOL Based on the EQ 5D Quest Health Status at Month 3 and 6
▼ Description:	Visual analogue scale to generate a self-perceived rating of health status. Visual analogue scale is the second part of the questionnaire, asking to mark health status on the day of the interview on a 20 cm vertical scale with end points of 0 and 100. There are notes at the both ends of the scale that the bottom rate (0) corresponds to " the worst health you can imagine", and the highest rate (100) corresponds to "the best health you can

	Imagine". Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0. If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

ITT population used. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	127	124
Mean (Standard Deviation) Unit of Measure: Score on a Scale		
Row Title		
Month 3	-2.33 (23.37)	-2.58 (27.14)
Month 6	-1.60 (24.02)	0.92 (30.22)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for EQ 5D Quest Health Status-Month 3

	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.525
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	2.18
	Confidence Interval	(2-Sided) 95% -4.56 to 8.93
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for EQ 5D Quest Health Status-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.995
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)

Estimated Value	0.02
Confidence Interval	(2-Sided) 95% -6.79 to 6.83
Estimation Comments	[Not specified]

18. Secondary Outcome

Title:	Change From Baseline in QOL Based on the Diabetes Symptom Checklist (DSC) at Month 3 and 6
▼ Description:	The Diabetes Symptoms Checklist was designed to assess the presence and perceived burden of diabetes-related symptoms. Respondents were to consider troublesomeness of 34 symptoms on a 5-point scale ranging from 5="extremely" to 1="not at all." For symptoms/side-effects not experienced, the item was scored as 0. Symptoms were grouped into the following subscales: psychological fatigue, psychological cognitive, neurology pain, neurology sensory, cardiology, ophthalmology, hypoglycemia, hyperglycemia. Subscale scores were calculated as the sum of the given subscale divided by the total number of items in the scale. Total score was computed from the sum of the 8 subscales and ranged from 0 to 40. Higher scores indicate greater symptom burden. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0. If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Baseline, Month 3, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

ITT population used. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.

Overall Number of Participants Analyzed	127	124
Mean (Standard Deviation) Unit of Measure: Scores on a scale		
Row Title		
Psychology, fatigue: Month 3	2.34 (20.73)	2.39 (20.33)
Psychology, fatigue: Month 6	2.48 (22.95)	-0.49 (24.64)
Psychology, cognitive: Month 3	0.16 (18.54)	2.66 (18.38)
Psychology, cognitive: Month 6	2.23 (18.87)	1.70 (17.23)
Neurology, pain: Month 3	-3.46 (17.87)	0.32 (19.18)
Neurology, pain: Month 6	-1.57 (21.09)	-1.75 (22.34)
Neurology, sensory: Month 3	-2.25 (16.96)	0.55 (16.09)
Neurology, sensory: Month 6	-0.19 (17.15)	-3.59 (15.76)
Cardiology: Month 3	1.18 (17.32)	0.87 (15.84)
Cardiology: Month 6	3.60 (17.74)	0.29 (18.11)
Ophthalmology: Month 3	1.53 (21.98)	2.24 (19.71)
Ophthalmology: Month 6	-0.26 (24.53)	0.23 (19.43)
Hypoglycemia: Month 3	0.49 (20.72)	0.12 (21.02)
Hypoglycemia: Month 6	0.50 (22.25)	-1.62 (21.72)
Hyperglycemia: Month 3	-2.07 (17.38)	-1.79 (18.83)
Hyperglycemia: Month 6	-0.79 (19.50)	-2.82 (18.25)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Psychology Fatigue-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.526
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.87
	Confidence Interval	(2-Sided) 95% -7.64 to 3.91
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Psychology Fatigue-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.779
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.83
	Confidence Interval	(2-Sided) 95% -5.01 to 6.68
	Estimation Comments	[Not specified]

ID: 31998 IMPENDIA- PEN VS Diamel Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

▼ Statistical Analysis 3

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Psychology Cognitive-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.246
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-2.95
	Confidence Interval	(2-Sided) 95% -7.95 to 2.04
	Estimation Comments	[Not specified]

▼ Statistical Analysis 4

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Psychology Cognitive-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.780
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.72
	Confidence Interval	(2-Sided) 95% -5.78 to 4.34
	Estimation Comments	[Not specified]

▼ Statistical Analysis 5 ✓

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Neurology Pain-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.885
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.41
	Confidence Interval	(2-Sided) 95% -5.22 to 6.04
	Estimation Comments	[Not specified]

▼ Statistical Analysis 6 ✓

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Neurology Pain-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.128
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	4.41
	Confidence Interval	(2-Sided) 95% -1.28 to 10.10
	Estimation Comments	[Not specified]

▼ Statistical Analysis 7 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Neurology Sensory-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
	P-Value	0.701

Statistical Test of Hypothesis	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	1.07
	Confidence Interval	(2-Sided) 95% -4.40 to 6.54
	Estimation Comments	[Not specified]

▼ Statistical Analysis 8 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Neurology Sensory-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.010
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	7.21
	Confidence Interval	(2-Sided) 95% 1.70 to 12.73
	Estimation Comments	[Not specified]

▼ Statistical Analysis 9 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Cardiology-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.934
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.20
	Confidence Interval	(2-Sided) 95% -4.63 to 5.03
	Estimation Comments	[Not specified]

▼ Statistical Analysis 10 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Cardiology-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
	P-Value	0.209

Statistical Test of Hypothesis	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	3.13
	Confidence Interval	(2-Sided) 95% -1.75 to 8.01
	Estimation Comments	[Not specified]

▼ Statistical Analysis 11 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Ophthalmology-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.585
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	1.89
	Confidence Interval	(2-Sided) 95% -4.90 to 8.68
	Estimation Comments	[Not specified]

▼ Statistical Analysis 12 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Ophthalmology-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.641
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	1.62
	Confidence Interval	(2-Sided) 95% -5.22 to 8.47
	Estimation Comments	[Not specified]

▼ Statistical Analysis 13 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Hypoglycemia-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]

	P-Value	0.586

Statistical Test of Hypothesis	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-1.50
	Confidence Interval	(2-Sided) 95% -6.89 to 3.90
	Estimation Comments	[Not specified]

▼ Statistical Analysis 14 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Hypoglycemia-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.906
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.33
	Confidence Interval	(2-Sided) 95% -5.79 to 5.14
	Estimation Comments	[Not specified]

▼ Statistical Analysis 15 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Hyperglycemia-Month 3
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.970
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.09
	Confidence Interval	(2-Sided) 95% -4.93 to 4.75
	Estimation Comments	[Not specified]

▼ Statistical Analysis 16 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Hyperglycemia-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
	P-Value	0.340

Statistical Test of Hypothesis	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	2.38
	Confidence Interval	(2-Sided) 95% -2.52 to 7.28
	Estimation Comments	[Not specified]

19. Secondary Outcome

Title:	Change From Baseline of MRI Body Composition at Month 6
▼ Description:	Values for Abdominal Subcutaneous Fat Volume and Abdominal Visceral Fat Volume are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

ITT of MRI sub-study (n=88 consented to participate), however, only a subset of MRI sub-study that had evaluable data were used in this analysis. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	39	43
Mean (Standard Deviation) Unit of Measure: mL		

ID: 31998 IMPENDIA-TREN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

Row Title		
Abdominal Visceral Fat Volume: Month 6 (n=38,43)	-49 (81.7)	-64.8 (73.2)
Abdominal Subcutaneous Fat Volume: Month 6	-12 (58.9)	-3.3 (70.2)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for Abdominal Subcutaneous Fat Volume-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.495
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	24.6
	Confidence Interval	(2-Sided) 95% -46.9 to 96
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means

		Comparing Treatment Groups for Abdominal Visceral Fat Volume-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.081
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	55.4
	Confidence Interval	(2-Sided) 95% -7 to 117.8
	Estimation Comments	[Not specified]

20. Secondary Outcome

Title:	Change From Baseline of Left Ventricular (LV) End Diastolic and Systolic Volume as Determined by MRI at Month 6
▼ Description:	Values for Left Ventricular (LV) End Diastolic and Systolic Volume are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 6 (End of Study)

▼ Outcome Measure Data

▼ Analysis Population Description

ITT of MRI sub-study (n=88 consented to participate),however, only a subset of MRI sub-study that had evaluable data were used.. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title		

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	39	43
Mean (Standard Deviation) Unit of Measure: mL		
Row Title		
LV End Diastolic Volume	2.1 (35.5)	0.7 (28.4)
LV End Systolic Volume	3.3 (28.1)	-0.2 (28.4)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for LV End Diastolic Volume-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.626
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	6.3
	Confidence Interval	(2-Sided) 95% -19.3 to 31.9

	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for LV End Systolic Volume-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.486
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	7.8
	Confidence Interval	(2-Sided) 95% -14.5 to 30.1
	Estimation Comments	[Not specified]

21. Secondary Outcome

Title:	Change From Baseline of Left Ventricular (LV) Mass Without and With Pap Muscles as Determined by MRI at Month 6
▼ Description:	Values for Left Ventricular (LV) Mass Without and With Pap Muscles are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

ITT of MRI sub-study (n=88 consented to participate), however, only a subset of MRI sub-study that had evaluable data were used.. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	39	43
Mean (Standard Deviation) Unit of Measure: grams		
Row Title		
LV Mass Without Pap Muscles	0.6 (38.4)	3.3 (26.5)
LV Mass With Pap Muscles	1.1 (39.2)	3.5 (26.6)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for LV Mass with Pap Muscles-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.832
	Comments	[Not specified]

	Method	ANOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	2.3
	Confidence Interval	(2-Sided) 95% -18.9 to 23.4
	Estimation Comments	[Not specified]

▼ Statistical Analysis 2 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for LV Mass without Pap Muscles-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.820
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	2.4
	Confidence Interval	(2-Sided) 95% -18.3 to 23.1
	Estimation Comments	[Not specified]

22. Secondary Outcome

ID: 31998 IMPENDIA- PEN VS Dianeal On Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

Title:	Change From Baseline of Left Ventricular (LV) Ejection Fraction as Determined by MRI at Month 6
▼ Description:	Values for Left Ventricular (LV) Ejection Fraction are included. Statistical analysis includes estimates of Least Squares (LS) comparing differences between treatment groups by visit and p-value using analysis of covariance (ANOVA) testing that the differences=0.
Time Frame:	Baseline, Month 6 (End of Study)

▼ Outcome Measure Data ✔

▼ Analysis Population Description

ITT of MRI sub-study (n=88 consented to participate), however, only a subset of MRI sub-study that had evaluable data were used.. The data in this outcome measure is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067).

Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description:	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
Overall Number of Participants Analyzed	39	42
Mean (Standard Deviation) Unit of Measure: Percent	-0.3 (8.2)	0.9 (10.4)

▼ Statistical Analysis 1 ✔

Statistical Analysis Overview	Comparison Group Selection	Non-Glucose Sparing Prescriptions, Glucose Sparing Prescriptions
	Comments	Estimate of Least Square Means Comparing Treatment Groups for LV Ejection Fraction-Month 6
	Type of Statistical Test	Superiority
	Comments	[Not specified]

ID: 31998 IMPENDIA- PEN VS Dianeal Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

Statistical Test of Hypothesis	P-Value	0.955
	Comments	[Not specified]
	Method	ANOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-0.2
	Confidence Interval	(2-Sided) 95% -6.9 to 6.5
	Estimation Comments	[Not specified]

Adverse Events

Time Frame		
Adverse Event Reporting Description	The data represented in this module is a pooled analysis of the following 3 studies: NCT00567489 (protocol ID 31998), NCT00567398 (protocol ID 34202), NCT01219959 (protocol ID51067). Given that the glucose content of the PD solutions is similar, the pooling of the results were considered a valid method to answer the underlying research questions.	
Source Vocabulary Name for Table Default	MedDRA 10.0	
Collection Approach for Table Default	Systematic Assessment	
Arm/Group Title	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
▼ Arm/Group Description	Dianeal only and/or Bieffe peritoneal dialysis (PD) solutions only	Physioneal, Extraneal, Nutrineal (PEN) used for 31998 and 34202 studies, and Dianeal, Extraneal, Nutrineal (DEN) used for 51067 study.
All-Cause Mortality		

	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
	Affected / at Risk (%)	Affected / at Risk (%)
Total	--- /---	--- /---

▼ **Serious Adverse Events**

	Non-Glucose Sparing Prescriptions	Glucose Sparing Prescriptions
	Affected / at Risk (%)	Affected / at Risk (%)
Total	41/127 (32.28%)	58/124 (46.77%)
Blood and lymphatic system disorders		
Anaemia †A	2/127 (1.57%)	2/124 (1.61%)
Cardiac disorders		
Acute Coronary Syndrome †A	0/127 (0%)	1/124 (0.81%)
Acute Myocardial Infarction †A	1/127 (0.79%)	0/124 (0%)
Angina Pectoris †A	2/127 (1.57%)	0/124 (0%)
Cardiac Arrest †A	0/127 (0%)	1/124 (0.81%)
Cardiac Failure Acute †A	1/127 (0.79%)	2/124 (1.61%)
Cardiorespiratory Arrest †A	0/127 (0%)	1/124 (0.81%)
Congestive Heart Failure †A	0/127 (0%)	1/124 (0.81%)
Coronary Artery Disease †A	1/127 (0.79%)	1/124 (0.81%)
Heart Failure †A	0/127 (0%)	1/124 (0.81%)
Ischemic Heart Disease †A	1/127 (0.79%)	0/124 (0%)
Ear and labyrinth disorders		
Deafness Neurosensory †A	0/127 (0%)	1/124 (0.81%)
Eye disorders		
Retinal Detachment †A	0/127 (0%)	1/124 (0.81%)
Gastrointestinal disorders		
Abdominal Discomfort †A	1/127 (0.79%)	0/124 (0%)
Abdominal Pain †A	1/127 (0.79%)	1/124 (0.81%)
Constipation †A	1/127 (0.79%)	1/124 (0.81%)
Gastrointestinal Haemorrhage †A	0/127 (0%)	1/124 (0.81%)

Gastroesophageal Reflux Disease †A	0/127 (0%)	1/124 (0.81%)
Intestinal Obstruction †A	0/127 (0%)	1/124 (0.81%)
Mallory-Weiss Syndrome †A	0/127 (0%)	1/124 (0.81%)
Peritonitis †A	2/127 (1.57%)	3/124 (2.42%)
Peritonitis Associated To Peritoneal Dialysis †A	0/127 (0%)	1/124 (0.81%)
Peritonitis By Capd †A	1/127 (0.79%)	1/124 (0.81%)
General disorders		
Asthenia †A	0/127 (0%)	1/124 (0.81%)
Catheter Related Complication †A	2/127 (1.57%)	1/124 (0.81%)
Catheter Site Haemorrhage †A	0/127 (0%)	1/124 (0.81%)
General Physical Health Deterioration †A	1/127 (0.79%)	0/124 (0%)
Generalised Oedema †A	1/127 (0.79%)	0/124 (0%)
Multi-Organ Failure †A	1/127 (0.79%)	0/124 (0%)
Non Specific Thoracic Pain †A	1/127 (0.79%)	0/124 (0%)
Non-Cardiac Chest Pain †A	0/127 (0%)	1/124 (0.81%)
Sudden Death †A	1/127 (0.79%)	0/124 (0%)
Thoracic Pain †A	1/127 (0.79%)	0/124 (0%)
Immune system disorders		
Hypersensitivity Icodextrin †A	0/127 (0%)	1/124 (0.81%)
Infections and infestations		
Abdominal Abscess †A	0/127 (0%)	1/124 (0.81%)
Abscess In Abdominal Wall †A	0/127 (0%)	1/124 (0.81%)
Abscess Limb †A	0/127 (0%)	1/124 (0.81%)
Bacterial Peritonitis †A	1/127 (0.79%)	1/124 (0.81%)
Cellulitis †A	1/127 (0.79%)	3/124 (2.42%)
Cellulitis Of Face †A	1/127 (0.79%)	0/124 (0%)
Cellulitis With Soft Tissue Necrosis Of The Right Hand †A	1/127 (0.79%)	0/124 (0%)
Entero Invasive Diarrhea †A	0/127 (0%)	1/124 (0.81%)
	0/127 (0%)	1/124 (0.81%)

Escherichia Coli Thigh Region [†A]		
Facial Abscess [†A]	1/127 (0.79%)	0/124 (0%)
Fungal Peritonitis [†A]	2/127 (1.57%)	1/124 (0.81%)
Gangrene [†A]	2/127 (1.57%)	0/124 (0%)
Gastroenteritis [†A]	2/127 (1.57%)	2/124 (1.61%)
Gastroenteritis Viral [†A]	1/127 (0.79%)	0/124 (0%)
Infection [†A]	0/127 (0%)	1/124 (0.81%)
Lower Respiratory Tract Infection [†A]	1/127 (0.79%)	0/124 (0%)
Necrotising Fasciitis [†A]	0/127 (0%)	1/124 (0.81%)
Nosocomial Pneumonia [†A]	0/127 (0%)	1/124 (0.81%)
Peritonitis Bacterial [†A]	5/127 (3.94%)	8/124 (6.45%)
Pneumonia [†A]	2/127 (1.57%)	2/124 (1.61%)
Post Traumatic Cellulitis [†A]	0/127 (0%)	1/124 (0.81%)
Right Basal Pneumonia [†A]	0/127 (0%)	2/124 (1.61%)
Sepsis [†A]	2/127 (1.57%)	1/124 (0.81%)
Thigh Abscess [†A]	0/127 (0%)	1/124 (0.81%)
Upper Respiratory Tract Infection [†A]	1/127 (0.79%)	0/124 (0%)
Urinary Tract Infection [†A]	3/127 (2.36%)	0/124 (0%)
Vestibular Neuronitis [†A]	1/127 (0.79%)	0/124 (0%)
Injury, poisoning and procedural complications		
Ankle Fracture [†A]	0/127 (0%)	1/124 (0.81%)
Contusion [†A]	0/127 (0%)	1/124 (0.81%)
Investigations		
Blood Glucose Abnormal [†A]	1/127 (0.79%)	0/124 (0%)
Metabolism and nutrition disorders		
Calciphylaxis [†A]	0/127 (0%)	1/124 (0.81%)
Dehydration [†A]	1/127 (0.79%)	1/124 (0.81%)
Diabetic Foot [†A]	1/127 (0.79%)	1/124 (0.81%)
Fluid Overload [†A]	3/127 (2.36%)	5/124 (4.03%)
Fluid Retention [†A]	1/127 (0.79%)	0/124 (0%)
Hypercalcaemia [†A]	2/127 (1.57%)	0/124 (0%)
Hyperglycaemia [†A]	2/127 (1.57%)	1/124 (0.81%)
Hypervolaemia [†A]	1/127 (0.79%)	1/124 (0.81%)

Hypoglycaemia †A	0/127 (0%)	2/124 (1.61%)
Hyponatraemia †A	0/127 (0%)	1/124 (0.81%)
Severe Hypoglycemia †A	0/127 (0%)	1/124 (0.81%)
Musculoskeletal and connective tissue disorders		
Gouty Arthritis †A	1/127 (0.79%)	0/124 (0%)
Soft Tissue Necrosis †A	1/127 (0.79%)	0/124 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Cervix Carcinoma †A	1/127 (0.79%)	0/124 (0%)
Nervous system disorders		
Cerebral Haemorrhage †A	1/127 (0.79%)	0/124 (0%)
Cerebral Ischaemia †A	1/127 (0.79%)	0/124 (0%)
Cerebrovascular Accident †A	1/127 (0.79%)	0/124 (0%)
Cognitive Disorder †A	0/127 (0%)	1/124 (0.81%)
Convulsion †A	0/127 (0%)	1/124 (0.81%)
Dizziness †A	1/127 (0.79%)	0/124 (0%)
Hypertensive Encephalopathy †A	0/127 (0%)	2/124 (1.61%)
Neurotoxicity †A	1/127 (0.79%)	0/124 (0%)
Seizure †A	0/127 (0%)	1/124 (0.81%)
Seizures †A	0/127 (0%)	1/124 (0.81%)
Sensory Impairment †A	0/127 (0%)	1/124 (0.81%)
Syncope †A	1/127 (0.79%)	1/124 (0.81%)
Thalamic Infarction †A	0/127 (0%)	1/124 (0.81%)
Transient Ischaemic Attack †A	1/127 (0.79%)	0/124 (0%)
Respiratory, thoracic and mediastinal disorders		
Pleural Effusion †A	0/127 (0%)	1/124 (0.81%)
Pulmonary Edema †A	0/127 (0%)	2/124 (1.61%)
Respiratory Arrest †A	0/127 (0%)	1/124 (0.81%)
Skin and subcutaneous tissue disorders		
Decubitus Ulcer †A	0/127 (0%)	1/124 (0.81%)
Diabetic Ulcer †A	1/127 (0.79%)	0/124 (0%)
	0/127 (0%)	1/124 (0.81%)

Erythema Multiforme †A		
Left Malleolus Ulcer †A	0/127 (0%)	1/124 (0.81%)
Local Infection Of The Skin (Diabetic Sore) †A	1/127 (0.79%)	0/124 (0%)
Rash †A	0/127 (0%)	1/124 (0.81%)
Skin Ulcer †A	0/127 (0%)	1/124 (0.81%)
Vascular disorders		
Blood Pressure Inadequately Controlled †A	1/127 (0.79%)	0/124 (0%)
Hypertension †A	0/127 (0%)	1/124 (0.81%)
Hypertensive Crisis †A	1/127 (0.79%)	3/124 (2.42%)
Hypertensive Urgency †A	0/127 (0%)	1/124 (0.81%)
Hypotension †A	1/127 (0.79%)	0/124 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

▼ Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	0%	
	Non-Glucose Sparing Prescriptions	**Glucose Sparing Prescriptions**
	Affected / at Risk (%)	Affected / at Risk (%)
Total	101/127 (79.53%)	98/124 (79.03%)
Blood and lymphatic system disorders		
Anaemia †A	6/127 (4.72%)	7/124 (5.65%)
Anemia †A	2/127 (1.57%)	1/124 (0.81%)
Cardiac disorders		
Acute Coronary Syndrome †A	0/127 (0%)	1/124 (0.81%)
Acute Myocardial Infarction †A	1/127 (0.79%)	0/124 (0%)
Angina Pectoris †A	2/127 (1.57%)	0/124 (0%)
Arteriosclerosis Coronary Artery †A	1/127 (0.79%)	0/124 (0%)
Cardiac Arrest †A	0/127 (0%)	1/124 (0.81%)
Cardiac Failure Acute †A	1/127 (0.79%)	2/124 (1.61%)
Cardiorespiratory Arrest †A	0/127 (0%)	1/124 (0.81%)

Congestive Heart Failure †A	0/127 (0%)	1/124 (0.81%)
Coronary Artery Disease †A	2/127 (1.57%)	1/124 (0.81%)
Heart Failure †A	0/127 (0%)	1/124 (0.81%)
Ischemic Heart Disease †A	1/127 (0.79%)	0/124 (0%)
Left Atrial Enlargement †A	1/127 (0.79%)	1/124 (0.81%)
Tachycardia †A	0/127 (0%)	1/124 (0.81%)
Ventricular Extrasystoles †A	0/127 (0%)	1/124 (0.81%)
Ear and labyrinth disorders		
Cerumen Impaction †A	1/127 (0.79%)	0/124 (0%)
Deafness Neurosensory †A	1/127 (0.79%)	1/124 (0.81%)
Ear Pain †A	0/127 (0%)	1/124 (0.81%)
Endocrine disorders		
Hyperparathyroidism †A	2/127 (1.57%)	1/124 (0.81%)
Hyperparathyroidism Secondary †A	1/127 (0.79%)	0/124 (0%)
Hyperthyroidism †A	0/127 (0%)	1/124 (0.81%)
Eye disorders		
Cataract †A	1/127 (0.79%)	0/124 (0%)
Diabetic Retinopathy †A	0/127 (0%)	1/124 (0.81%)
Dry Eye †A	2/127 (1.57%)	0/124 (0%)
Eye Haemorrhage †A	1/127 (0.79%)	0/124 (0%)
Eye Pain †A	1/127 (0.79%)	1/124 (0.81%)
Eye Pruritus †A	0/127 (0%)	1/124 (0.81%)
Glaucoma †A	1/127 (0.79%)	1/124 (0.81%)
Myodesopsia †A	1/127 (0.79%)	0/124 (0%)
Retinal Detachment †A	0/127 (0%)	1/124 (0.81%)
Visual Acuity Reduced †A	1/127 (0.79%)	0/124 (0%)
Vitreous Haemorrhage †A	0/127 (0%)	1/124 (0.81%)
Gastrointestinal disorders		
Abdominal Discomfort †A	1/127 (0.79%)	0/124 (0%)
Abdominal Distension †A	1/127 (0.79%)	1/124 (0.81%)
Abdominal Pain †A	3/127 (2.36%)	5/124 (4.03%)

Abdominal Pain Upper †A	0/127 (0%)	1/124 (0.81%)
Acute Diarrhea †A	0/127 (0%)	1/124 (0.81%)
Bloating †A	0/127 (0%)	1/124 (0.81%)
Bloody Peritoneal Effluent †A	1/127 (0.79%)	0/124 (0%)
Constipation †A	4/127 (3.15%)	8/124 (6.45%)
Diabetic Gastropathy †A	1/127 (0.79%)	0/124 (0%)
Diarrhea †A	2/127 (1.57%)	0/124 (0%)
Diarrhoea †A	4/127 (3.15%)	1/124 (0.81%)
Dyspepsia †A	0/127 (0%)	3/124 (2.42%)
Epigastric Pain †A	2/127 (1.57%)	0/124 (0%)
Gastric Ulcer Haemorrhage †A	1/127 (0.79%)	0/124 (0%)
Gastritis †A	0/127 (0%)	1/124 (0.81%)
Gastroduodenitis †A	0/127 (0%)	1/124 (0.81%)
Gastrointestinal Haemorrhage †A	0/127 (0%)	1/124 (0.81%)
Gastrooesophageal Reflux Disease †A	0/127 (0%)	1/124 (0.81%)
Hyperemesis †A	1/127 (0.79%)	0/124 (0%)
Impaired Gastric Emptying †A	1/127 (0.79%)	0/124 (0%)
Inguinal Hernia †A	0/127 (0%)	1/124 (0.81%)
Intestinal Obstruction †A	0/127 (0%)	1/124 (0.81%)
Mallory-Weiss Syndrome †A	0/127 (0%)	2/124 (1.61%)
Nausea †A	6/127 (4.72%)	4/124 (3.23%)
Nauseas †A	0/127 (0%)	1/124 (0.81%)
Odynophagia †A	0/127 (0%)	1/124 (0.81%)
Pain In Teeth †A	0/127 (0%)	1/124 (0.81%)
Peptic Ulcer †A	1/127 (0.79%)	0/124 (0%)
Peritoneal Haemorrhage †A	0/127 (0%)	1/124 (0.81%)
Peritonitis †A	10/127 (7.87%)	10/124 (8.06%)
Peritonitis Associated To Peritoneal Dialysis †A	0/127 (0%)	1/124 (0.81%)
Peritonitis By Cap †A	1/127 (0.79%)	0/124 (0%)
Peritonitis By Capd †A	1/127 (0.79%)	2/124 (1.61%)
Reflux Oesophagitis †A	0/127 (0%)	1/124 (0.81%)
Umbilical Hernia †A	1/127 (0.79%)	1/124 (0.81%)
Vomiting †A	4/127 (3.15%)	9/124 (7.26%)

Application Site Oedema †A	0/127 (0%)	1/124 (0.81%)
Asthenia †A	0/127 (0%)	4/124 (3.23%)
Catheter Related Complication †A	4/127 (3.15%)	4/124 (3.23%)
Catheter Site Discharge †A	1/127 (0.79%)	1/124 (0.81%)
Catheter Site Haemorrhage †A	0/127 (0%)	1/124 (0.81%)
Chest Discomfort †A	1/127 (0.79%)	1/124 (0.81%)
Chills †A	0/127 (0%)	1/124 (0.81%)
General Physical Health Deterioration †A	1/127 (0.79%)	0/124 (0%)
Generalised Oedema †A	1/127 (0.79%)	0/124 (0%)
Granuloma †A	1/127 (0.79%)	0/124 (0%)
Granuloma In Exit-Site †A	0/127 (0%)	1/124 (0.81%)
Granuloma Of The Exit Site †A	0/127 (0%)	1/124 (0.81%)
Influenza Like Illness †A	0/127 (0%)	1/124 (0.81%)
Injection Site Papule †A	1/127 (0.79%)	0/124 (0%)
Mild Erythema Of Catheter Exit Site †A	0/127 (0%)	1/124 (0.81%)
Multi-Organ Failure †A	1/127 (0.79%)	0/124 (0%)
Non Specific Thoracic Pain †A	1/127 (0.79%)	0/124 (0%)
Non-Cardiac Chest Pain †A	0/127 (0%)	1/124 (0.81%)
Oedema †A	8/127 (6.3%)	0/124 (0%)
Oedema Peripheral †A	10/127 (7.87%)	2/124 (1.61%)
Peritoneal Catheter Dysfunction †A	1/127 (0.79%)	0/124 (0%)
Pyrexia †A	0/127 (0%)	2/124 (1.61%)
Sickness †A	1/127 (0.79%)	1/124 (0.81%)
Sudden Death †A	1/127 (0.79%)	0/124 (0%)
Thirst †A	1/127 (0.79%)	0/124 (0%)
Thoracic Pain †A	1/127 (0.79%)	0/124 (0%)
Xerosis †A	1/127 (0.79%)	0/124 (0%)
Hepatobiliary disorders		
Cholelithiasis †A	1/127 (0.79%)	0/124 (0%)

Hepatitis Toxic †A	0/127 (0%)	1/124 (0.81%)
Immune system disorders		
Hypersensitivity Icodextrin †A	0/127 (0%)	1/124 (0.81%)
Skin Allergic Reaction †A	0/127 (0%)	1/124 (0.81%)
Infections and infestations		
Abdominal Abscess †A	0/127 (0%)	1/124 (0.81%)
Abscess In Abdominal Wall †A	0/127 (0%)	1/124 (0.81%)
Abscess Limb †A	0/127 (0%)	1/124 (0.81%)
Bacterial Peritonitis †A	2/127 (1.57%)	1/124 (0.81%)
Candidiasis †A	0/127 (0%)	1/124 (0.81%)
Catheter Site Infection †A	5/127 (3.94%)	5/124 (4.03%)
Cellulitis †A	1/127 (0.79%)	3/124 (2.42%)
Cellulitis Of Face †A	1/127 (0.79%)	0/124 (0%)
Cellulitis With Soft Tissue Necrosis Of The Right Hand †A	1/127 (0.79%)	0/124 (0%)
Diarrhoea Infectious †A	0/127 (0%)	1/124 (0.81%)
Entero Invasive Diarrhea †A	0/127 (0%)	1/124 (0.81%)
Eschar In The Left Thigh Region †A	0/127 (0%)	1/124 (0.81%)
Exit Site Infection †A	1/127 (0.79%)	1/124 (0.81%)
Exit Site Infection Of Catheter †A	0/127 (0%)	1/124 (0.81%)
Facial Abscess †A	1/127 (0.79%)	0/124 (0%)
Flu †A	2/127 (1.57%)	2/124 (1.61%)
Folliculitis †A	0/127 (0%)	1/124 (0.81%)
Fungal Peritonitis †A	2/127 (1.57%)	1/124 (0.81%)
Gangrene †A	2/127 (1.57%)	0/124 (0%)
Gastroenteritis †A	3/127 (2.36%)	2/124 (1.61%)
Gastroenteritis Viral †A	1/127 (0.79%)	0/124 (0%)
Herpes Virus Infection †A	0/127 (0%)	1/124 (0.81%)
Herpes Zoster †A	2/127 (1.57%)	1/124 (0.81%)
Infection †A	0/127 (0%)	1/124 (0.81%)
Localised Infection †A	0/127 (0%)	1/124 (0.81%)
Lower Respiratory Tract Infection †A	2/127 (1.57%)	2/124 (1.61%)
Nasopharyngitis †A	0/127 (0%)	2/124 (1.61%)

Necrotising Fasciitis †A	0/127 (0%)	1/124 (0.81%)
Nosocomial Pneumonia †A	0/127 (0%)	1/124 (0.81%)
Oral Herpes †A	0/127 (0%)	1/124 (0.81%)
Orchitis †A	1/127 (0.79%)	0/124 (0%)
Otitis Externa †A	1/127 (0.79%)	0/124 (0%)
Peritonitis Bacterial †A	7/127 (5.51%)	8/124 (6.45%)
Pharyngitis †A	0/127 (0%)	1/124 (0.81%)
Pneumonia †A	3/127 (2.36%)	2/124 (1.61%)
Post Traumatic Cellulitis †A	0/127 (0%)	1/124 (0.81%)
Respiratory Tract Infection Viral †A	1/127 (0.79%)	0/124 (0%)
Rhinitis †A	0/127 (0%)	1/124 (0.81%)
Right Basal Pneumonia †A	0/127 (0%)	2/124 (1.61%)
Sepsis †A	2/127 (1.57%)	1/124 (0.81%)
Severe Acute Respiratory Syndrome †A	1/127 (0.79%)	0/124 (0%)
Skin Infection †A	0/127 (0%)	1/124 (0.81%)
Skin Infection Staphylococcus †A	0/127 (0%)	1/124 (0.81%)
Syphilis †A	1/127 (0.79%)	0/124 (0%)
Thigh Abscess †A	0/127 (0%)	1/124 (0.81%)
Tonsillitis †A	1/127 (0.79%)	0/124 (0%)
Upper Respiratory Tract Infection †A	2/127 (1.57%)	4/124 (3.23%)
Urinary Infection †A	0/127 (0%)	1/124 (0.81%)
Urinary Tract Infection †A	6/127 (4.72%)	2/124 (1.61%)
Vestibular Neuronitis †A	1/127 (0.79%)	0/124 (0%)
Viral Infection †A	0/127 (0%)	1/124 (0.81%)
Vulvovaginal Candidiasis †A	0/127 (0%)	1/124 (0.81%)
Wound Infection †A	1/127 (0.79%)	0/124 (0%)
Injury, poisoning and procedural complications		
Ankle Fracture †A	0/127 (0%)	1/124 (0.81%)
Bitten By A Dog On The Left Leg †A	1/127 (0.79%)	0/124 (0%)
Contusion †A	0/127 (0%)	1/124 (0.81%)
Dialysis Device Complication †A	0/127 (0%)	1/124 (0.81%)

Excoriation †A	0/127 (0%)	1/124 (0.81%)
Excoriation On Knees †A	1/127 (0.79%)	0/124 (0%)
Fracture Right Leg †A	1/127 (0.79%)	0/124 (0%)
Incisional Hernia †A	2/127 (1.57%)	0/124 (0%)
Joint Sprain †A	0/127 (0%)	1/124 (0.81%)
Trauma Of Soft Tissue †A	0/127 (0%)	1/124 (0.81%)
Investigations		
Blood Alkaline Phosphatase Increased †A	1/127 (0.79%)	0/124 (0%)
Blood Calcium Decreased †A	1/127 (0.79%)	0/124 (0%)
Blood Glucose Abnormal †A	1/127 (0.79%)	0/124 (0%)
Blood Magnesium Decreased †A	1/127 (0.79%)	0/124 (0%)
Blood Parathyroid Hormone Increased †A	2/127 (1.57%)	0/124 (0%)
Blood Phosphorus Decreased †A	0/127 (0%)	1/124 (0.81%)
Blood Urea Increased †A	1/127 (0.79%)	0/124 (0%)
Decreased Peripheral Pulses †A	0/127 (0%)	1/124 (0.81%)
Electrocardiogram T Wave Inversion †A	2/127 (1.57%)	0/124 (0%)
Fibrin Abnormal †A	0/127 (0%)	1/124 (0.81%)
Haemoglobin Increased †A	1/127 (0.79%)	0/124 (0%)
Heart Murmur †A	1/127 (0.79%)	0/124 (0%)
Liver Function Test Abnormal †A	0/127 (0%)	1/124 (0.81%)
St Segment Depression †A	1/127 (0.79%)	0/124 (0%)
T Peaked †A	0/127 (0%)	1/124 (0.81%)
Urine Output Decreased †A	1/127 (0.79%)	0/124 (0%)
Weight Increased †A	0/127 (0%)	1/124 (0.81%)
Metabolism and nutrition disorders		
Calciphylaxis †A	0/127 (0%)	1/124 (0.81%)
Decreased Appetite †A	2/127 (1.57%)	1/124 (0.81%)
Dehydration †A	2/127 (1.57%)	4/124 (3.23%)

Diabetes Mellitus Inadequate Control [†A]	1/127 (0.79%)	0/124 (0%)
Diabetic Foot [†A]	3/127 (2.36%)	1/124 (0.81%)
Dyslipidaemia [†A]	1/127 (0.79%)	0/124 (0%)
Dyslipidemia [†A]	0/127 (0%)	1/124 (0.81%)
Fluid Imbalance [†A]	1/127 (0.79%)	1/124 (0.81%)
Fluid Overload [†A]	6/127 (4.72%)	8/124 (6.45%)
Fluid Retention [†A]	2/127 (1.57%)	0/124 (0%)
Gout [†A]	2/127 (1.57%)	0/124 (0%)
Hypercalcaemia [†A]	5/127 (3.94%)	3/124 (2.42%)
Hypercholesterolaemia [†A]	1/127 (0.79%)	1/124 (0.81%)
Hyperglycaemia [†A]	3/127 (2.36%)	4/124 (3.23%)
Hyperglycemia [†A]	1/127 (0.79%)	1/124 (0.81%)
Hyperkalaemia [†A]	1/127 (0.79%)	1/124 (0.81%)
Hyperlipidaemia [†A]	2/127 (1.57%)	1/124 (0.81%)
Hyperphosphataemia [†A]	0/127 (0%)	3/124 (2.42%)
Hyperphosphatemia [†A]	1/127 (0.79%)	0/124 (0%)
Hypertriglyceridaemia [†A]	1/127 (0.79%)	0/124 (0%)
Hypervolaemia [†A]	3/127 (2.36%)	1/124 (0.81%)
Hypervolemia [†A]	2/127 (1.57%)	0/124 (0%)
Hypoalbuminaemia [†A]	0/127 (0%)	1/124 (0.81%)
Hypoalbuminemia [†A]	1/127 (0.79%)	1/124 (0.81%)
Hypocalcaemia [†A]	0/127 (0%)	2/124 (1.61%)
Hypocalcemia [†A]	0/127 (0%)	1/124 (0.81%)
Hypoglycaemia [†A]	1/127 (0.79%)	10/124 (8.06%)
Hypoglycemia [†A]	3/127 (2.36%)	1/124 (0.81%)
Hypokalaemia [†A]	3/127 (2.36%)	3/124 (2.42%)
Hypomagnesaemia [†A]	0/127 (0%)	1/124 (0.81%)
Hyponatraemia [†A]	0/127 (0%)	2/124 (1.61%)
Hypoproteinaemia [†A]	1/127 (0.79%)	0/124 (0%)
Hyporexia [†A]	1/127 (0.79%)	3/124 (2.42%)
Hypovolaemia [†A]	0/127 (0%)	2/124 (1.61%)
Iron Deficiency [†A]	0/127 (0%)	1/124 (0.81%)
Malnutrition [†A]	3/127 (2.36%)	5/124 (4.03%)
Mild Malnutrition [†A]	0/127 (0%)	2/124 (1.61%)
Moderate Malnutrition [†A]	2/127 (1.57%)	0/124 (0%)
Polydipsia [†A]	1/127 (0.79%)	0/124 (0%)
Severe Hypoglycemia [†A]	0/127 (0%)	1/124 (0.81%)

Musculoskeletal and connective tissue disorders		
Arthralgia [†A]	1/127 (0.79%)	0/124 (0%)
Arthritis [†A]	0/127 (0%)	1/124 (0.81%)
Back Pain [†A]	1/127 (0.79%)	0/124 (0%)
Gouty Arthritis [†A]	1/127 (0.79%)	0/124 (0%)
Groin Pain [†A]	1/127 (0.79%)	0/124 (0%)
Joint Swelling [†A]	1/127 (0.79%)	0/124 (0%)
Ligamentitis [†A]	0/127 (0%)	1/124 (0.81%)
Lower Back Pain [†A]	1/127 (0.79%)	0/124 (0%)
Lower Limbs Cramp [†A]	1/127 (0.79%)	0/124 (0%)
Muscle Spasms [†A]	1/127 (0.79%)	2/124 (1.61%)
Myalgia [†A]	0/127 (0%)	2/124 (1.61%)
Neck Pain [†A]	1/127 (0.79%)	0/124 (0%)
Osteoarthritis [†A]	0/127 (0%)	1/124 (0.81%)
Pain In Bilateral Legs [†A]	0/127 (0%)	1/124 (0.81%)
Pain In Extremity [†A]	0/127 (0%)	2/124 (1.61%)
Right Knee Osteoarthritis [†A]	1/127 (0.79%)	0/124 (0%)
Soft Tissue Necrosis [†A]	1/127 (0.79%)	0/124 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Carcinoid Tumour Of The Duodenum [†A]	1/127 (0.79%)	0/124 (0%)
Cervix Carcinoma [†A]	1/127 (0.79%)	0/124 (0%)
Squamous Cell Carcinoma [†A]	0/127 (0%)	1/124 (0.81%)
Nervous system disorders		
Burning Sensation [†A]	1/127 (0.79%)	0/124 (0%)
Cerebral Haemorrhage [†A]	1/127 (0.79%)	0/124 (0%)
Cerebral Ischaemia [†A]	1/127 (0.79%)	0/124 (0%)
Cerebrovascular Accident [†A]	1/127 (0.79%)	0/124 (0%)
Cognitive Disorder [†A]	0/127 (0%)	1/124 (0.81%)
Convulsion [†A]	0/127 (0%)	1/124 (0.81%)
Diabetic Encephalopathy [†A]	1/127 (0.79%)	0/124 (0%)

Diabetic Neuropathy †A	1/127 (0.79%)	0/124 (0%)
Dizziness †A	2/127 (1.57%)	2/124 (1.61%)
Headache †A	0/127 (0%)	3/124 (2.42%)
Hypertensive Encephalopathy †A	0/127 (0%)	2/124 (1.61%)
Hypoaesthesia †A	0/127 (0%)	3/124 (2.42%)
Hypoesthesia Hands And Feet †A	0/127 (0%)	1/124 (0.81%)
Neurotoxicity †A	1/127 (0.79%)	0/124 (0%)
Paraesthesia †A	2/127 (1.57%)	0/124 (0%)
Restless Legs Syndrome †A	1/127 (0.79%)	0/124 (0%)
Seizure †A	0/127 (0%)	1/124 (0.81%)
Seizures †A	0/127 (0%)	1/124 (0.81%)
Sensory Impairment †A	0/127 (0%)	1/124 (0.81%)
Syncope †A	1/127 (0.79%)	1/124 (0.81%)
Thalamic Infarction †A	0/127 (0%)	1/124 (0.81%)
Third Cranial Nerve Neuropathy †A	0/127 (0%)	1/124 (0.81%)
Transient Ischaemic Attack †A	1/127 (0.79%)	0/124 (0%)
Psychiatric disorders		
Anxiety †A	2/127 (1.57%)	0/124 (0%)
Depression †A	1/127 (0.79%)	1/124 (0.81%)
Insomnia †A	2/127 (1.57%)	4/124 (3.23%)
Sadness †A	0/127 (0%)	1/124 (0.81%)
Renal and urinary disorders		
Nephrolithiasis †A	1/127 (0.79%)	0/124 (0%)
Respiratory, thoracic and mediastinal disorders		
Bronchospasm †A	1/127 (0.79%)	0/124 (0%)
Chronic Obstructive Pulmonary Disease †A	0/127 (0%)	1/124 (0.81%)
Cough †A	6/127 (4.72%)	3/124 (2.42%)
Dyspnoea †A	0/127 (0%)	1/124 (0.81%)
Hiccups †A	1/127 (0.79%)	0/124 (0%)
Oropharyngeal Pain †A	2/127 (1.57%)	0/124 (0%)
Pleural Effusion †A	0/127 (0%)	1/124 (0.81%)
Productive Cough †A	1/127 (0.79%)	1/124 (0.81%)
Pulmonary Edema †A	0/127 (0%)	2/124 (1.61%)
Rales †A	0/127 (0%)	1/124 (0.81%)
Respiratory Arrest †A	0/127 (0%)	1/124 (0.81%)

Rhinitis Allergic †A	0/127 (0%)	1/124 (0.81%)
Rhinorrhoea †A	1/127 (0.79%)	0/124 (0%)
Skin and subcutaneous tissue disorders		
Acne †A	1/127 (0.79%)	0/124 (0%)
Blister †A	1/127 (0.79%)	1/124 (0.81%)
Decubitus Ulcer †A	0/127 (0%)	1/124 (0.81%)
Diabetic Ulcer †A	1/127 (0.79%)	0/124 (0%)
Erythema †A	1/127 (0.79%)	0/124 (0%)
Erythema Multiforme †A	0/127 (0%)	1/124 (0.81%)
Excessive Granulation Tissue †A	3/127 (2.36%)	0/124 (0%)
Exfoliative Dermatitis †A	0/127 (0%)	1/124 (0.81%)
Hyperkeratosis †A	1/127 (0.79%)	1/124 (0.81%)
Hypopigmented Skin Lesions †A	0/127 (0%)	1/124 (0.81%)
Left Malleolus Ulcer †A	0/127 (0%)	1/124 (0.81%)
Local Infection Of The Skin (Diabetic Sore) †A	1/127 (0.79%)	0/124 (0%)
Nail Discolouration †A	0/127 (0%)	1/124 (0.81%)
Pruritus †A	3/127 (2.36%)	6/124 (4.84%)
Psoriasis †A	0/127 (0%)	2/124 (1.61%)
Rash †A	0/127 (0%)	4/124 (3.23%)
Skin Exfoliation †A	0/127 (0%)	1/124 (0.81%)
Skin Lesion †A	0/127 (0%)	1/124 (0.81%)
Skin Ulcer †A	1/127 (0.79%)	1/124 (0.81%)
Swelling Face †A	0/127 (0%)	1/124 (0.81%)
Surgical and medical procedures		
Arteriovenous Fistula Operation †A	0/127 (0%)	1/124 (0.81%)
Dialysis †A	1/127 (0.79%)	0/124 (0%)
Vascular disorders		
Accelerated Hypertension †A	1/127 (0.79%)	0/124 (0%)
Arterial Hypertension †A	0/127 (0%)	1/124 (0.81%)
Arterial Stenosis †A	1/127 (0.79%)	0/124 (0%)
Arteriosclerosis Obliterans †A	1/127 (0.79%)	0/124 (0%)
	1/127 (0.79%)	0/124 (0%)

† A		
Diabetic Vascular Disorder † A	1/127 (0.79%)	0/124 (0%)
Digital Ischemia In The 1st And 2nd Of The Feet † A	0/127 (0%)	1/124 (0.81%)
Haematoma † A	1/127 (0.79%)	0/124 (0%)
Hypertension † A	10/127 (7.87%)	6/124 (4.84%)
Hypertensive Crisis † A	1/127 (0.79%)	3/124 (2.42%)
Hypertensive Urgency † A	0/127 (0%)	1/124 (0.81%)
Hypotension † A	4/127 (3.15%)	2/124 (1.61%)
Ischaemia † A	1/127 (0.79%)	0/124 (0%)
Jugular Vein Distension † A	0/127 (0%)	1/124 (0.81%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

Limitations and Caveats

This is a pooled analysis of NCT00567489, NCT00567398, and NCT01219959. Given that the glucose content of the PD solutions were similar, the pooling of the results were considered a valid method to answer the underlying research questions.

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact

Name/Official Title:	Clinical Trials Disclosure Group
Organization:	Baxter Healthcare Corporation

ID: 31998 IMPENDE: PEN VS Diamea-Only Improved Metabolic Control In Diabetic CAPD and APD Patients NCT00567489

Phone: (224) 948-7359
Email: Global_CORP_ClinicalTrialsDisclosure@baxter.com