# EFFECT OF LOW GLUCOSE DEGRADATION PRODUCT (GDP) PERITONEAL DIALYSIS SOLUTION GAMBROSOL TRIO® ON RESIDUAL RENAL FUNCTION IN PATIENTS RECEIVING PERITONEAL DIALYSIS – A Randomized Trial

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## Introduction

Residual renal function correlates with mortality and morbidity rates in dialysis-dependent patients. It is also a key contributor to peritoneal dialysis technique success.

# **Purpose**

We examined whether the use of a biocompatible peritoneal dialysis solution (Gambrosol Trio®) delayed residual renal function decline in incident dialysis patients with GFR

# **Methods**

Patients with glomerular filtration rates of greater than 1 mL/minute were randomized (by minimization to equally distribute variables of centre, CHF and diabetes histories) to receive Gambrosol Trio® (a biocompatible solution with low levels of glucose degradation products) or standard peritoneal dialysis solutions (Baxter solutions) for 2 years.

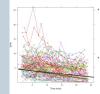
A repeated measures MANCOVA was used to evaluate differences in residual renal function between the two groups for all patients with 3 or more GFR determinations.

## Results



Variable	Gambrosol Trio®	Standard
Number	50	49
Male	29	30
Age (years(SD))	59.68 (1.56)	58,51 (1.60)
Oriental	38	29
Caucasian	3	6
Black	2	2
South Asian	7	10
Other	0	2
Number of patients in Hong Kong	22	17
History of Diabetes Mellitus	25	26
History of Congestive Heart Failure	16	26
Present or past smoker	19	15
Cause of kidney disease		
Diabetic Nephropathy	8	10
Chronic Glomerulonephritis	12	9
Systemic Lupus	2	0
Polycystic Kidney Disease	0	1
Hypertension	4	4
Other/Unknown	24	2.5
Urine Volume (milliliters per day)	1518.98 (83.35)	1598.16 (95.95)
Proteinuria (grams per day)	2.91 (0.41)	3.40 (0.45)
Urine creatinine clearance (ml/min)	9.60 (0.60)	8.80 (0.64)
Urine urea clearance (ml/min)	4.80 (0.37)	4.37 (0.27)
Mean GFR (ml/min/1.73 m2)	7.27 (0.47)	6.58 (0.44)
Hemoglobin (grams/1)	101.44 (2.33)	103.10 (2.12)
Serum Phosphate (mmol/1)	1.70 (0.06)	1.76 (0.06)
Serum Albumin (mg/l)	32.86 (0.71)	33.37 (0.72)
CRP (units)	7.57 (0.88)	11.87 (2.99)
Weekly Peritoneal CrCl	40.96 (1.20)	41.87 (1.28)
Weekly Peritoneal KtV	1.40 (0.05)	1.46 (0.05)
Peritoneal D/PCr	0.76 (0.01)	0.74 (0.01)
Dialysis-CA125 (units)	0.82 (0.06)	0.73 (0.06)
Dialysis-Hyaluronan (units)	0.85 (0.05)	0.75 (0.06)
Systolic BP (mmHg)	138.00 (2.12)	140.14 (2.64)
Diastolic BP (mmHg)	72.24 (1.49)	74.78 (1.85)
BMI	24.95 (0.65)	25.19 (0.79)
Weight (kg)	64.7184 (2.0710)	66.87 (2.37)
TBW mass by BIA	34.540 (1.157)	35.99 (1.10)
Fat mass by BIA	245.820 (1.6159)	23.92 (1.39)
PCR	0.99 (0.04)	1.03 (0.04)

## Primary Outcome: Rates of Residual Renal Function Decline



Glomerular filtration rates declined at a rate of 0.1160 (+/-0.024) mL/ minute per month in the Gambrosol Trio® arm, and 0.1678 (+/-0.023) in the Standard Arm
Difference in rates of

#### Difference in rates of decline was 0.0518 mL/ minute per month, p=0.113.

## **Results**

## Secondary Outcome: Rates of Urine Volume Decline



Utine volumes declined at a rate of 15.15 (+/-5.44) mt/day per month in the Gambrosol Trio® arm, and 25.76 (+/-5.20) mt/day per month in the Standard Arm

Difference in rates of decline was 10.61 mt/day per month, p=0.1583.

## Table 3: Other Secondary Outcomes

Variable	Gambrosel Trio®		Significance of Difference
Use of icodestran* (number of patients)	4	14	(p=0.2339) chi sq test
Ultrafiltration failure** (number of patients)	0	3	(p=1.0) fisher's exact test
Peritoritis - number of - episodes/number - of patients with - peritoritis	53/27=1.96	22/15=1.47	(p=0.3012) Exact Rate Ratio Test
<ul> <li>number of parients/breatment group</li> </ul>	27/50=0.54	1549-0.31	(p=0.0315)*** 2-sample test for equality of two monortions

\*coclection was not available in the Hong Kong cobort "4-defined as utilistalization both and 100m albert 4 hour dwell with 2.5% destroos solution on a PET test, occurring more than a year after starting PD, with UP's most 100 mM 4 hours in the first year.
\*\*\* p0-0.0 fit adjusted using the Benferroni correction for multiple testing.

## Conclusion

Compared with standard peritoneal dialysis solutions, the use of Gambrosol Trio® resulted in clinically, but not statistically, significant slower declines in residual renal function and 24-hour urine volumes.