Simultaneous increase in ultrafiltration volume and sodium removal with steady concentration peritoneal dialysis using Carry Life UF

Triomed

Martin Wilkie[1], Jörgen Hegbrant[2], Charlotte de Leon[3], Ola Carlsson[3], Olof Heimbürger[4]

1. Sheffield Teaching Hospitals, Sheffield, United Kingdom. 2. Division of Nephrology, Department of Clinical Sciences, Lund University, Lund, Sweden. 3. Triomed AB, Lund, Sweden. 4. Medical Unit Renal Medicine, Karolinska University Hospital and CLINTEC, Karolinska Institute, Stockholm, Sweden.

Introduction

Achieving adequate ultrafiltration (UF) as well as adequate sodium removal is a challenge with peritoneal dialysis (PD), especially during automated PD (APD), as a result of sodium sieving. Carry Life UF is a novel PD system (Figure 1), using steady concentration peritoneal dialysis (SCPD), that is potentially suitable for PD patients requiring enhanced fluid removal. The Carry Life UF device transfers small amounts of dialysate between the patient and the device, while continuously adding glucose to achieve a stable intraperitoneal glucose concentration during the treatment. The aim of this study was to investigate ultrafiltration, sodium removal and glucose efficiency using Carry Life UF.

Methods

- Eight stable PD patients were included in the study
- Subjects were treated with 5-hour Carry Life UF treatments at three different glucose doses (11, 14, 20 g/h)
- An initial fill with 1.5 liters, 1.36% glucose PD solution was used.
- A standard 4-hour 2.27% glucose 2 liters CAPD dwell was used as control
- UF volume, sodium removal, and glucose absorption was calculated as well as glucose efficiency for UF (ml UF volume/g glucose absorbed), and for sodium removal (mmol sodium removed/g glucose absorbed)
- Data expressed as mean ± SD, statistical analysis using one-way ANOVA, * p<0.05, ** p<0.01, *** p<0.001

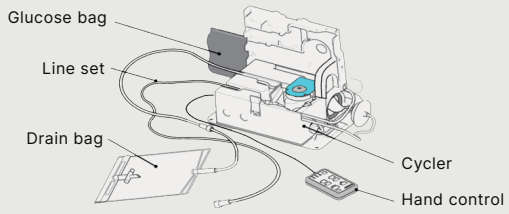

Figure 1 Line diagram of the Carry Life UF system: Cycler, Line set and Glucose bag

Results

The results from the control and the Carry Life UF treatments are shown in the table and figures below. The most important findings were:

- Dialysate glucose concentration decreased with the 2.27% glucose CAPD dwell, whereas it with the Carry Life UF increased during the first 1–2 hours and then remained stable
- Dialysate sodium concentration only had a small initial decline during the 2.27% glucose CAPD dwell but decreased continuously during the Carry Life UF treatments
- Compared to the control:
  - UF volume was 4-5 times higher with Carry Life UF
  - UF volume per gram of glucose absorbed was 2-3 times higher with Carry Life UF
  - Sodium removal per gram of glucose absorbed was 2-3 times higher with Carry Life UF
- There was a strong correlation between UF volume and sodium removal for the Carry Life UF treatments

Conclusion

- SCPD performed with the Carry Life UF system resulted in higher UF, greater and predictable sodium removal and more efficient use of glucose, both with respect to UF and sodium removal
- A stable dialysate glucose concentration with the Carry Life UF resulted in increased UF
- An increased sodium gradient between plasma and dialysate contributes to a greater diffusive sodium removal with the Carry Life UF
- The Carry Life UF is a promising novel PD system that has the potential to address the clinical needs to increase fluid and sodium removal in PD

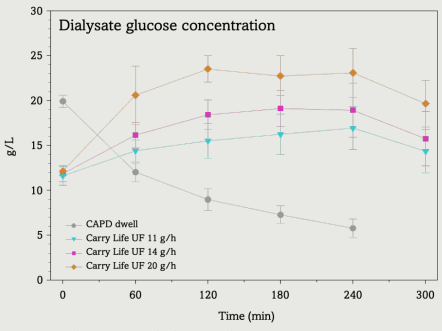

Figure 2 Changes in dialysate glucose concentration

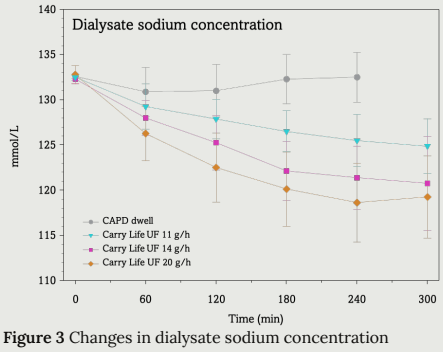

Figure 3 Changes in dialysate sodium concentration

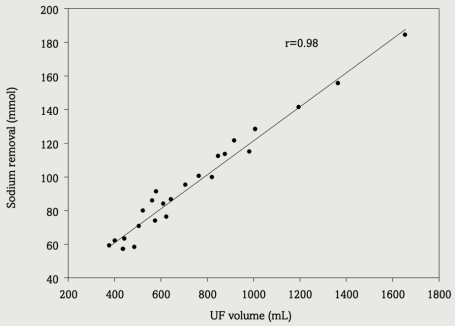

Figure 4 Dialytic sodium removal as a function of UF volume; Data from 24 Carry Life UF treatments at three different doses

Treatment		UF volume (mL/dwell)	Sodium removal (mmol/ dwell)	Glucose absorption (g/dwell)	Glucose UF efficiency (mL/g glucose absorbed)	Glucose sodium removal efficiency (mmol/g glucose absorbed)
Control (2.27% CAPD dwell, 4h)		162±242	21±33	32±4.2	5.9±7.8	0.78±1.04
Carry Life UF, 5h	11 g/h	646±256***	86±27***	43±9.3**	17.0±10.6**	2.23±1.20**
	14 g/h	739±312***	92±33***	53±4.4***	14.5±7.7**	1.80±0.82*
	20 g/h	863±380***	110±37***	73±7.1***	12.4±6.8*	1.57±0.69

Table 1 Study results

WCN25-AB-917
Trial registration number:
NCT03724682
(ClinicalTrials.gov)

Reference
Heimburger O, Hegbrant J, Martus G, Wilkie M, De Leon C, Carlsson O, Johansson AC: Effects of Steady Glucose Concentration Peritoneal Dialysis on Ultrafiltration Volume and Sodium Removal: A Pilot Crossover Trial. Clin J Am Soc Nephrol 2023, 19(2):224-232; 10.2215/CJN.0000000000000342.

The Carry Life UF system is not commercially available

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Design of a prospective, multicenter, randomized, cross-over study of the Carry Life UF system in continuous ambulatory peritoneal dialysis (CAPD) patients in the home setting

Triomed

Martin Wilkie[1], Jörgen Hegbrant[2], Charlotte de Leon[3], Ola Carlsson[3], Olof Heimbürger[4]

1. Sheffield Teaching Hospitals, Sheffield, United Kingdom. 2. Division of Nephrology, Department of Clinical Sciences, Lund University, Lund, Sweden. 3. Triomed AB, Lund, Sweden. 4. Medical Unit Renal Medicine, Karolinska University Hospital and CLINTEC, Karolinska Institute, Stockholm, Sweden.

Introduction

Carry Life UF is a novel technology that provides treatment with steady concentration peritoneal dialysis (SCPD) i.e., maintains the glucose concentration in the dialysate for the entire duration of the treatment to obtain an efficient ultrafiltration (UF) and sodium removal. The aim of this study is to assess the efficacy and safety of the Carry Life UF device system (Figure 1) in the home setting. Collection of accurate data in a home environment requires a carefully designed protocol and providing research nursing support for patient training and end-point data collection. (NCT05874804, ClinicalTrials.gov)

Study design

Study type: A prospective, multicenter (Italy, Sweden, UK), randomized, crossover study of adult end-stage kidney disease patients

Study duration: Approximately 12 weeks per participant

Primary endpoint: UF volume, comparing the control CAPD 2.27% glucose dwell with the Carry Life UF treatment, measured at two specific treatments during each arm of the home phase

Secondary endpoints: Adverse events, peritoneal sodium removal, glucose UF efficiency, peak dialysate glucose concentration

Study size: 19 participants required to complete the study

Key inclusion criterion:

A PD prescription of 2–4 CAPD dwells/day unchanged for a minimum of two weeks, with at least one 1.5–2 L, 2.27% glucose day dwell daily

Key exclusion criteria:

- An episode of peritonitis within the last three months
- Clinical signs of dehydration
- Systolic blood pressure < 100 mmHg within the last month

In-clinic phase (3 visits):

- Peritoneal solute transfer rate classification (PET)
- Two Carry Life UF treatment (11 g/h or 15 g/h glucose dose with an initial fill of 1.36% glucose PD solution)
- Hourly dialysate measurements for peak dialysate glucose concentration and dialysate sodium concentration

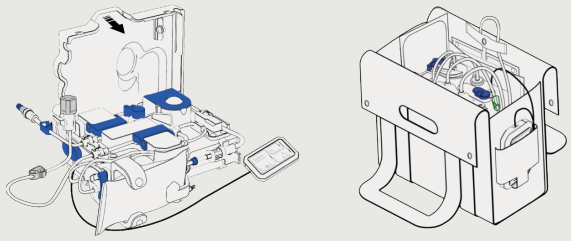

Figure 1 Line diagram of the Carry Life UF system

Home phase:

- Control arm - 4 weeks on standard PD prescription
- Carry Life UF arm - 4 weeks with three Carry Life UF treatments per week replacing three 2.27% glucose dwells; the remaining four days, one 2.27% glucose dwell daily is replaced with a 1.36% glucose dwell

Ensuring accurate assessment of study endpoint

Correct determination of UF volumes in PD studies is a challenge. Detailed weighing and sampling instructions are provided to the study centers to ensure accurate data quality. Measures to ensure reliable endpoint data include:

- Weighing of the CAPD Y-set fill bag performed after the flush and before the fill
- Weighing and sampling of the CAPD Y-set drain bags performed before the flush-before-fill procedure,
- Plastic material weight considered in the fluid volume calculations
- Study centers provided detailed weighing instructions, such as how to place the bags on the scale and weighing the bags with or without overwrap
- Specially trained study nurses to visit the participants for bag weighing and sampling to obtain reliable data for the endpoint analyses

Economic compensation to participants

Due to the significant burden associated with this device trial and enable a smooth recruitment process, it is important to offer study participants a fair compensation, in accordance with local regulations

Study activities considered when determining compensation:

- Three in-clinic treatments (whole day visits)
- Two to five Carry Life UF training sessions
- Twelve Carry Life UF treatments at home (60 hours plus preparation)
- 56 days filling out diary (body weight, blood pressure, PD solutions, drain bag weights)
- Three 24-hour urine collections
- Two end-of arm visits to the clinic

Conclusion

This study sets out to evaluate a novel PD technology based on SCPD.

The study places a considerable burden on the participants, furthermore, the execution of the study in the home environment entails challenges both in ensuring accurate endpoint data recording and in providing necessary support to the subjects in the use of the technology.

Our protocol has been carefully designed to attend to these issues and to optimize the possibility of the study reaching its stated goals.

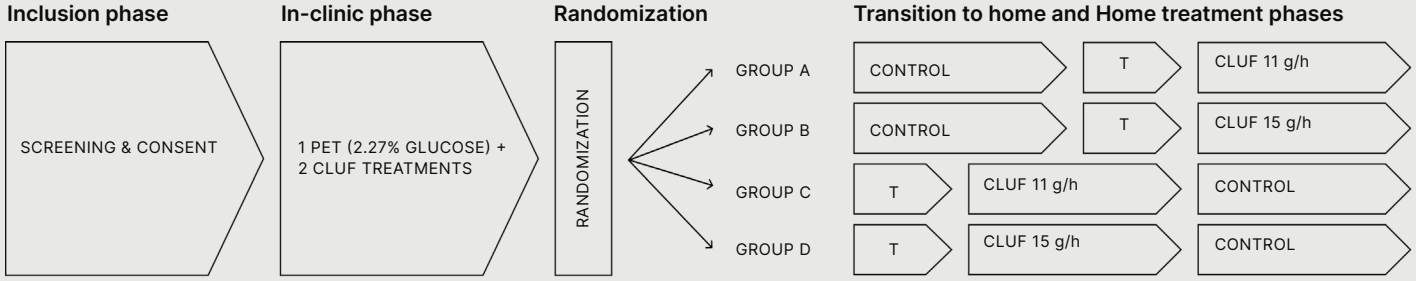

Figure 2 Flow chart presenting the phases of the study.
CLUF = Carry Life UF, PET = peritoneal equilibration test, T = device training

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The Carry Life UF system is not commercially available

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