# 60th Medical Group (AMC), Travis AFB, CA

## INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

## FINAL REPORT SUMMARY

**(Please type all information. Use additional pages if necessary.)**

**PROTOCOL #:** FDG20180007A **DATE:** 24 Jan 19

**PROTOCOL TITLE:** A Swine (Sus Scrofa) Peritoneal Dialysis Model Using a Novel Potassium Adsorbing Polymer for the Treatment of Severe Hyperkalemia.

**PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC):** Dr. Guillaume Hoareau

**DEPARTMENT:** SGSE **PHONE #:** (215) 275-0395

**INITIAL APPROVAL DATE:** 15 Feb 18 **LAST TRIENNIAL REVISION DATE:** N/A

**FUNDING SOURCE:** Air Force Surgeon General's Office

1. **RECORD OF ANIMAL USAGE:**

| Animal Species: | Total # Approved | # Used this FY | Total # Used to Date |
|---|---|---|---|
| *Sus scrofa* | 18 | 13 | 13 |
| | | | |
| | | | |

2. **PROTOCOL TYPE / CHARACTERISTICS:** (Check all applicable terms in **EACH** column)

| | | |
|---|---|---|
| ___ Training: Live Animal | ___ Medical Readiness | ___ Prolonged Restraint |
| ___ Training: non-Live Animal | ___ Health Promotion | ___ Multiple Survival Surgery |
| ___ Research: Survival (chronic) | ___ Prevention | ___ Behavioral Study |
| _X__ Research: non-Survival (acute) | ___ Utilization Mgt. | ___ Adjuvant Use |
| ___ Other ( ) | __X_ Other (Treatment ) | ___ Biohazard |

3. **PROTOCOL PAIN CATEGORY (USDA):** (Check applicable) ___ C __X_ D ___ E

4. **PROTOCOL STATUS:**

***Request Protocol Closure:**

___ Inactive, protocol never initiated

___ Inactive, protocol initiated but has not/will not be completed

_X__ Completed, all approved procedures/animal uses have been completed

5. **Previous Amendments:**
List all amendments made to the protocol. **IF none occurred, state NONE. Do not use N/A.**

**For the Entire Study Chronologically**

| Amendment Number | Date of Approval | Summary of the Change |
|---|---|---|
| 1 | 11 Jul 18 | Personnel |
| 2 | 10 Sep 18 | Personnel |
| | | |

6. **FUNDING STATUS:** Funding allocated: $ 32,445.00 Funds remaining: $ 0.00

7. **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? ___ Yes _x_ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

**ADDITIONS:** (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

| NAME | PROTOCOL FUNCTION | IACUC APPROVAL |
|---|---|---|
| | | |
| | | |

**DELETIONS:** (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

| NAME | PROTOCOL FUNCTION | DATE OF DELETION |
|---|---|---|
| | | |
| | | |

8. **PROBLEMS / ADVERSE EVENTS:** We did not identify significant concerns.

9. **REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:**

**REPLACEMENT (ALTERNATIVES):** None to date.

**REFINEMENT:** None to date.

**REDUCTION:** None to date.

10. **PUBLICATIONS / PRESENTATIONS:** The results of this experiments are being analyzed and have therefore not been submitted for publication yet. We anticipate submission to a journal such as the American Journal of Disaster Medicine or Military Medicine.

11. **PROTOCOL OBJECTIVES:** The objectives were met. While we demonstrated that the investigational device was able to remove potassium from the dialysate over the course of the experiment, there was no significant difference in serum potassium concentration between the intervention and control groups.

12. **PROTOCOL OUTCOME SUMMARY:** (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

**Objectives:** We hypothesize that 1- peritoneal dialysis with our investigational device will result in decreased systemic potassium concentrations compared with sham peritoneal dialysis, and 2- peritoneal dialysis with the same device will not result in significant hypocalcemia or hypomagnesemia.

**Materials and methods:** Ten pigs were anesthetized and instrumented. Two peritoneal dialysis catheters were inserted. Following bilateral nephrectomy, animals received intravenous potassium chloride and were randomized to the control or treatment group. In both groups, 2 liters of peritoneal dialysate were infused in the abdomen. Four exchanges were performed with a dwell time of 1 hour. The peritoneal dialysate was retrieved over 20 minutes and re-infused over 10 minutes. In the intervention group, the dialysate was returned into a bag containing the investigational potassium binding beads. In the control group, the dialysate was retrieved and returned into and from the same empty plastic bag. Blood samples were obtained throughout the experiment.

**Results:** While there was a significant increase in plasma potassium concentration overall ($p<0.001$), there was no difference between groups ($p=0.99$) (Figure 1). Similar findings were observed for plasma total calcium concentration. There was no difference in plasma total magnesium concentration between groups or over time. The mean (+/- standard deviation) percent volume of dialysate retrieved after each exchange was significantly lower in the treatment group when compared to the control group (83.4 +/- 11.1 % and 91.1 +/- 6.4 %, respectively). Potassium concentration was non-detectable after all but one exchange in the intervention group. For that specific exchange the potassium concentration was reduced by 74%.

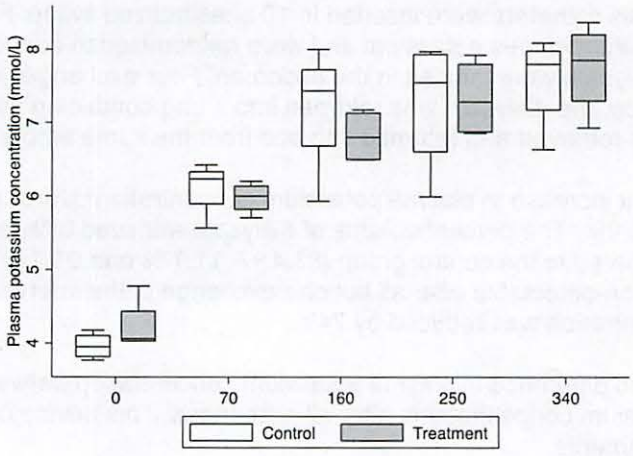


*Figure1. Plasma potassium concentration over time.*

**Conclusion:** While there was no difference in plasma potassium concentration, the investigational device significantly reduced dialysate potassium concentrations after all exchanges. Future studies should focus on improving dialysate retrieval fractions after dwells in the treatment group and evaluate longer experimental times. The investigational device could significantly reduce dialysate requirements in austere environments.

**(PI / TC Signature)**

3/13/19
**(Date)**

**Attachments:**
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission **(Mandatory)**

**Attachment 1**

**Defense Technical Information Center (DTIC) Abstract Submission**

**This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.**

**Objectives:** Peritoneal dialysis with our investigational device will decrease systemic potassium concentrations compared with sham.

**Methods:** Two peritoneal dialysis catheters were inserted in 10 anesthetized swine. Following bilateral nephrectomy, animals received intravenous potassium and were randomized to control or treatment group. In both groups, 2 liters of peritoneal dialysate were infused in the abdomen. Four exchanges were performed with a 1-hour dwell time. In the treatment group, the dialysate was returned into a bag containing potassium binding beads. In the control group, the dialysate was retrieved and returned into and from the same empty bag.

**Results:** There was a significant increase in plasma potassium concentration overall ($p<0.001$); there was no difference between groups ($p=0.99$). The percent volume of dialysate retrieved after each exchange was lower in the treatment group when compared to the control group (83.4 +/- 11.1 % and 91.1 +/- 6.4 %, respectively). Potassium concentration was non-detectable after all but one exchange in the intervention group. For that specific exchange the potassium concentration was reduced by 74%.

**Conclusion:** While there was no difference in plasma potassium concentration between groups, the investigational device reduced dialysate potassium concentrations after all exchanges. This device could minimize dialysate requirements in austere environments.

**Grant Number:**_____

**From:**_____

****If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**