COVER PAGE FOR PROTOCOL AND STATISTICAL ANALYSIS PLAN

Official Study Title: A Randomized Controlled Trial for Optimal Feeding Tube Placement

NCT number: NCT

IRB Approval Date: 11-21-17

Unique Protocol ID: HSC20170704H

Protocol Form: A Randomized Controlled Trial for Optimal Feeding Tube Placement

Item 1 UTHSCSA Tracking Number	HSC20170704H

Item 2 Abstract / Project Summary	Provide a succinct and accurate description of the proposed research. State the purpose/aims. Describe concisely the research design and methods for achieving the stated goals. This section should be understandable to all members of the IRB, scientific and non-scientific. **DO NOT EXCEED THE SPACE PROVIDED**.

Purpose/Objectives: Define the optimal method to place an enteral feeding tube. Our objective is to perform a randomized controlled trial of two different methods of tube placement with outcomes of cost, safety, radiation exposure, and the time.

Research Design/Plan: A randomized controlled trial comparing current standard blind method to CORTRAK enteral access system (CEAS), an FDA approved electromagnetic device to place enteric tubes.

Methods: Patient population would include patients in pediatric intensive care unit, pediatric cardiac unit, intermediate medical care unit and pediatric floor who receives postpyloric feeding tube placements. We are going to monitor total time and number attempts required for each successful placement, correlation of findings on x-ray versus CEAS, cost-effectiveness of this new equipment with standard blind method and decrease in radiation exposure with CEAS.

Clinical Relevance: For insertion of post-pyloric tube, standard blind technique is the most commonly used method. We plan to compare this routine methods with another FDA approved method of feeding tube placement using electromagnetic guidance. Our goal will be to determine if the electromagnetic method decreases the number of attempts, duration of time, and the number of x-rays needed to place a feeding tube. Recent retrospective adult and pediatric studies document promising results with minimal complications using this technique.

Item 3 Background	
Describe past experimental and/or clinical findings leading to the formulation of your study. *For research involving unapproved drugs, describe animal and human studies.* *For research that involves approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol.*	Insert background: Children admitted to PICU are undernourished 40-60% of times due to poor feeding tolerance. Critical illness is a catabolic stress state and nutritional requirements are much higher. Primary methods of nutrition delivery are parenteral nutrition (PN) and enteral nutrition(EN). Enteral feeding is preferable whenever possible as it is more physiological and more cost-effective without the added risk of nosocomial infection inherent with parenteral nutrition (PN). Two major routes of enteral nutrition are gastric feeding and postpyloric feeding. Because postpyloric EN reduces gastric residue, it reduces the risk of pulmonary aspiration and aspiration pneumonia. Postpyloric feeding has been shown to be associated with significantly lesser risk of pneumonia and vomiting as well as increased in total percentage of nutrition delivered compared to gastric tube feeding in critically ill patients. From our review of last 6 months' patient charts in last 6 months, there were 85 incidences of postpyloric feeding tube placement in 46 patients and total 194 x-rays were done to confirm placement, averaging 2.3 X-rays per placement attempt.
Item 4 Purpose and rationale *Insert purpose, objectives and research questions/hypotheses here. If you cut and paste from another document, make sure the excerpted material answers the question*	Purpose: We hypothesize that enteric feeding tube placement under electromagnetic guidance using CEAS (Cortrak Enteral Access System) is superior to current standard blind technique. We wish to expand on previous studies to conclusively define that CEAS decreases number of attempts, total time and radiation exposure required during an accurate postpyloric feeding tube placement. Rationale: Previous studies have conclusively shown that standard blind technique is associated with higher number of attempts, longer total time duration and more x-rays for confirmation as compared to CEAS. None of the

	previous studies have been randomized though. We are planning to carry out a randomized controlled trial to evaluate CEAS more reliably and nullify population bias if any. *October et al, Pediatr Crit Care Med 2009 Vol. 10, No. 2: Successful placement of postpyloric enteral tubes using electromagnetic guidance in critically ill children.* *Brown et al, American Journal of Critical Care, May 2017, Volume 26, No. 3: Use of electromagnetic device to insert postpyloric feeding tubes in a pediatric intensive care unit* *Goggans et al, Nutrition in Clinical Practice Volume 32 Number 2 April 2017 233 – 237, Transpyloric Feeding Tube Placement Using Electromagnetic Placement Device in Children*

Item 5 Study Population(s) Being Recruited In your recruitment plan, how many different populations of prospective subjects do you plan to target? Provide number: 100		
e.g., a population can be individuals with type 2 diabetes controlled with diet and/or a population of healthy controls. Or a population can be individuals attending an education program, etc. List each different population on a separate row and provide a short descriptive **label**: *(e.g., normal-healthy, diabetics, parents, children, etc.)* *To add rows use copy & paste*	Identify the criteria for **inclusion**:	Identify the criteria for **exclusion**:
- Children admitted to pediatric Floor, IMC, PICU and pediatric cardiac ICU who need a postpyloric feeding tube	- Patient admitted to pediatric floor, IMC, pediatric ICU or pediatric cardiac ICU requiring postpyloric feeding tube placement of size 8F or more and not meeting any of exclusion criteria	- Open chest wall - Open abdominal wall

Item 6 **Research Plan / Description of the Research Methods *a.*** *Provide a **comprehensive narrative** describing the **research methods**.* *Provide the **plan for data analysis** (include as applicable the **sample size calculation**).*	
uq	Step-by-Step Methods: We intend to conduct a randomized controlled trial comparing current standard blind technique to CORTRAK enteral access system (CEAS), the electromagnetic device to place enteric tubes. Both techniques are FDA approved and being used across the country. University hospital has recently purchased the CEAS and we have already used it to placed feeding tube in children. CEAS uses same feeding tube that is currently being used at UHS,. The stylet used with CEAS has a small magnetic tip to generate a signal captured by the receiver placed on the patient's lower chest.. Receiver is connected to a monitor which shows the path of feeding tube as it advances during insertion. Blind technique uses the same tube and same stylet except the

nurse places the tube by moving the patient around.

When a patient in pediatrics needs a post pyloric feeding tube, we approach the parents to explain the need for adequate nutrition in safe manner. After the clinical discussion, the parents will be informed that we are comparing 2 different methods of placement to determine which one can be completed with less attempts and x-rays to confirm placement. As previous studies have documented safety and efficacy of this technique we will be performing a prospective randomized trial. Patients will be randomized using sealed envelopes in a locked box, prepared by a person not part of this study. We are planning to form a team of total 11 nurses (covering both day and night shifts) to be the super users for feeding tube placement. Each member will be trained with the new equipment for a period of 1-2 weeks before getting involved in the study. The identity of the nurses inserting feeding tube will not be collected. Feeding tube placement will occur per randomization. Regardless of method used, per local clinical practice, a chest xray is obtained to verify placement. If the tube is not shown to be placed correctly (regardless of the placement method), the tube will be repositioned, and another xray is taken until confirmation is obtained that the tube is in proper place. Data collection sheet (attached with this form), monitoring total time and attempts required, will be completed for every participant. An enrollment log will match a unique identifier assigned to each participant with their demographic information. All data will be entered and maintained on UTHSCSA REDCap server the remaining information (e.g., enrollment log and data sheet) will be in locked cabinet. Each successful placement will be considered 1 event. After placement if the feeding tube comes out accidentally or the child pulls it out, child will go through the randomization process again for repeat placement and new event will be considered as a new subject. At the time of analysis, we will carry out separate analysis for all subjects with initial placement and repeat placement. We are also going to monitor correlation of findings on x-ray versus CEAS and how closely CEAS predicts correct location confirmed by an x-ray post-placement. We will compare cost-effectiveness of this new equipment with standard blind method. We are going to analyze if using CEAS brings radiation exposure down significantly for enteric tube placement. If statistically significant, we will start a separate study to analyze if CEAS can be substitute for x-ray confirmation and if the current practice of x-ray confirmation can be discontinued. Device has the FDA clearance for feeding tube placement without an X-ray confirmation. Concurrently, we will gather clinical data on secondary outcomes that include intensive care unit stay, hospital stay, mechanical ventilation days, reason for admission and time to achieve full feeds, previous gastrointestinal (GI) procedures or surgeries.

Data Analysis Plan: We will make all attempts to standardize the patients within each group. Meaning, we recognize that a healthy child with no significant past medical history may not be comparable to a child with caustic ingestion or a child with history of esophageal stricture or previous esophageal surgeries or a child with severe scoliosis. Within each of the groups of standard blind technique and CORTRAK Enteral Access System (CEAS) patients, we will index the results to the Pediatric Risk of Mortality (PRISM) score. To determine the difference between the two methods we performed a power analysis on our hypothesis that CEAS method will decrease radiation exposure, time to placement, and cost compared to the blind technique. The standard (two-sided) F-test of association between CEAS and blind technique placement will yield a power of 86% given 40 subjects with a Type I error of 0.05. We made this power calculation using PASS 2008 (NCSS, LLC. Kaysville, Utah). For each of the populations we are interested we will enroll a minimum of 100 individuals. At 30 patients, we will perform a mid-study analysis to decide how long the study needs to continue.

Item 7 Risks Section:

Complete the following table to describe the risks of all **research procedures** listed in Step 2, Institutional Form (items 28-34). *Do not list risks of Routine care procedures here.*

☐ N/A, Risks are described in the informed consent document – do not complete this table.

Research procedures *example:* • History and physical • Questionnaire • Laboratory tests *Add or delete rows as needed*	**Risks** List the reasonably expected risks under the following categories as appropriate:
Placement of device over child's chest and abdomen	Serious and likely; ○ none Serious and less likely; ○ none Serious and rare; ○ none ○ Not serious and likely; none Not serious and less likely ○ none
Insertion of a feeding tube (no difference between both procedures)	Serious and likely; ○ none Serious and less likely; ○ none Serious and rare; ○ Perforation of bowel ○ misplacement into lungs leading to pneumonitis Not serious and likely; ○ Discomfort to the child Not serious and less likely ○ none
Data collection	Serious and likely; ○ none Serious and less likely; ○ none Serious and rare; ○ none Not serious and likely; ○ none Not serious and less likely ○ Confidentiality breach