Children's Mercy KANSAS CITY

NIH STUDY INVESTIGATES TRANSITION FROM TUBE TO ORAL FEEDINGS

Children's Mercy Researcher Examines Impact on Gut Microbiome

PREVALENCE OF CHILDREN WITH FEEDING TUBES AND CHALLENGES

According to a 2017 study published in *Nutrition Clinical Practice*, about 40% of all individuals with feeding tubes are children.[1]

Although tube feeding saves the lives of children who do not eat orally, chronic tube feeding can be a burden to patients, caregivers and families, making the transition to oral feeding an important goal.

Existing treatment options for this transition include outpatient, inpatient and day treatment programs. Outpatient treatment delivered by a multidisciplinary team during clinic visits is the most widely available.

NIH FUNDS STUDY ON WEANING PATIENTS FROM TUBE TO ORAL FEEDING

Ann M. Davis, PhD, MPH, ABPP, Director, Center for Children's Healthy Lifestyles & Nutrition at Children's Mercy Kansas City and Ralph L. Smith Professor of Pediatrics at the University of Kansas Medical Center, is leading iKanEat, a novel interdisciplinary outpatient protocol for transitioning children from tube to oral feeding.

The five-year study is funded by the National Institutes of Health. Sarah Edwards, DO, Director, Multidisciplinary Feeding Clinic, and Jose Cocjin, MD, Chief, Section of Neurogastroenterology and Motility, are conducting the study and enrolling patients at Children's Mercy Kansas City.

Study sites began recruiting patients in August 2019, with the goal of enrolling 72 patients total. To date, Children's Mercy has enrolled five patients, the largest number of any participating institution.

iKanEat PROTOCOL EFFECTIVE

Previous data suggest the iKanEat protocol is effective for transitioning tube-fed children to eating by mouth. The original iKanEat study included two medications: amitriptyline, an antidepressant; and megestrol, an appetite stimulant.

The team's work demonstrated that amitriptyline is not a necessary component of the protocol, because all children who completed the protocol consumed 100% of their calories orally post treatment, regardless of whether they received amitriptyline or placebo. Amitriptyline was subsequently removed from the protocol.[2]

The current protocol is a randomized controlled trial of megestrol compared to placebo. It is assessing whether a four-week course of megestrol improves outcomes within the iKanEat protocol.

"The iKanEat intensive tube weaning program utilizes a combination of outpatient and telehealth visits, versus the traditional inpatient or day treatment program. It also is a unique opportunity to analyze the impact of this transition on the gut microbiome." – Dr. Edwards

CONCURRENTLY EXAMINING GUT MICROBIOTA

Little is known about the gut microbiota of children who transition from formula to oral feeding. That's why Dr. Edwards saw this as an opportunity to determine how the gut microbiome adapts to changes in diet over time in children who transition from commercial or blended formulas to an oral diet.

Dr. Edwards has received supplemental funding from the Center for Healthy Lifestyles & Nutrition and the Children's Mercy Division of Gastroenterology to examine this important question. This arm of the research is running concurrently with the NIH study.

Dr. Edwards with a patient in the Multidisciplinary Feeding Clinic.

None of the children enrolled in the NIH study will change their current dietary formulations, but the gut microbiome aspect of the study hypothesizes that the transition to oral feeding will increase the variety of foods consumed orally, leading to a more diverse gut microbiome by week 24. It also theorizes that children on a blended diet formula at week zero will have a more diverse microbiome than children on a commercially prepared formula prior to transitioning to oral feeding.

This research could add to general knowledge about how the gut microbiome adapts to changes in diet over time in children who transition from commercial or blended formulas to an oral diet.

TRANSITIONING FROM TUBE FEEDINGS

The iKanEat protocol combines outpatient clinic and telemedicine visits, providing benefits to patients and families including reduced risk of complications, such as infection, and improvements in quality of life.

The 24-week iKanEat intervention includes four in-person clinic visits at participating sites and 12 remote telemedicine visits. Stool samples for the microbiota arm of the study are collected at the in-person visits.

Remote sessions utilize the videoconferencing app Zoom on a computer or tablet, or are conducted over the phone. During weeks 1-10, the caregiver works with a feeding specialist on the remote feeding calls to improve the child's feeding skills.

At week 10, the child begins to transition off tube feedings. The child is given either the megestrol or placebo to take at this time. The caregiver reduces the child's tube feedings by 10% each day over 10 days, until the child is completely off tube feeding.

POTENTIAL TO TRANSFORM CLINICAL CARE

The iKanEat study will conclude in 2023. Though its primary purpose is to investigate the role of the appetite stimulant megestrol, according to Dr. Edwards, the outpatient/remote access weaning program being used is unique and could lead to changes in treatment protocols for children transitioning from tube to oral feeding.

The supplemental study regarding the gut microbiome may shed new light on the effect of the transition from tube to oral feeding on the gut microbiome.

REFERENCES

[1] Prevalence of Home Parenteral and Enteral Nutrition in the United States. Mundi MS, Pattinson A, McMahon MT, Davidson J, Hurt RT. Nutr Clin Pract. 2017 Dec;32(6):799-805. doi: 10.1177/0884533617718472. Epub 2017 Jul 17.

[2] iKanEat: Study Protocol for a Randomized Controlled Trial of Megestrol for Children with Feeding Problems. Edwards S, Hyman PE, Mousa H, Bruce A, Cocjin J, Dean K, Fleming K, Swinburne Romine R, Davis AM. Submitted to BMJ Open.

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