Neuromodulation for Children with Cystic Fibrosis Experiencing Chronic Abdominal Pain
NCT05515250
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STUDY PROTOCOL: Eligible participants will be recruited from the gastroenterology or Cystic Fibrosis clinics at Cardinal Glennon Hospital, Saint Louis University and Saint Louis Children's Hospital at Washington University in Saint Louis. Consent to participate and a detailed history, physical examination and laboratory tests for stool calprotectin will be obtained at the participants' clinical management site. A global assessment of abdominal pain will be used to rate its severity. Participants will be allowed to continue medication regimens that they are on prior to enrollment. No adjustments in medications will be allowed during the 3-week study period unless deemed necessary by the CF care team. Also, no new medications or OTC treatments will be allowed during the 3-weeks trial of PENFS unless deemed necessary by the CF care team. The use of all medications will be carefully monitored each week for future evaluation.

Following screening evaluation, enrolled participants will complete questionnaires and have the initial PENFS device placed by a trained health care professional. Device placement will then be done at the gastroenterology clinic at Cardinal Glennon Hospital to which participants will return every 7 days for a total of 3 visits for device replacement and completion of questionnaires. Three different devices will be placed in total (at baseline, at the end of week 1, and at the end of week 2). Following each visit and at week 8, participants will complete follow-up pain, CFQ-R, IBS-SSS, and PedsQL GI symptom scale administered in person by the study clinical coordinator at the clinical management site. The PI and sub-investigators at each clinical site will review adverse events on a continual basis to watch for unexpected safety signals.

Table 1 presents the expected timeline. The total length of the study, from screening of the first participant to the end of the study, is expected to be approximately 12 months

	Screening/ baseline	End of Week 1	End of Week 2	End of Week 4 **	8-week follow-up **
Informed Consent/enrollment	X				
Eligibility assessment	X				
Demography and Medical history	X				
Check Current Medication	X	X	X	X	X
IB-Stim Placement	**X**	**X**	**X**		
Pain Score*	X	X	X	X	X
CFQ-R*	X	X	X	X	X
IBS-SSS*	X	X	X	X	X
PedsQL GI symptom scale Version 3.0*	X	X	X	X	X
Stool Calprotectin	X[a]			X[b]	

STATISTICAL PLAN(in conjunction with the AHEAD Institute at St. Louis University): The primary endpoint for this study is the change in the abdominal pain scores from baseline to study exit. The secondary endpoints will be the change in the IBS-SSS (Symptoms Severity Scale), CFQ-R, and PedsQL Gastrointestinal symptom scale from baseline to study exit. The median pain scores will be computed at the three time points in the study (baseline, at 4 weeks and at 8 weeks) and compared using the non-parametric Kruskal Wallis test. Ad-hoc pairwise comparisons will be done using the Dwass, Steel, Critchlow-Fligner multiple comparison procedure (10,11). Trends in these indices over time will be compared using mixed models adjusting for repeated measures. These statistics will also be computed for the secondary endpoints. REDCap (Research Electronic Data Capture), a secure web-based application or password protected excel, will be used for data management and storage. P-values < 0.05 are considered significant. All analysis will be two-sided and completed in SAS 9.4 or the current version of SAS at the time of the study (SAS Institute Inc., Cary, NC, USA).

Due to less-than-optimal numbers of participants, this study was closed after enrolling one patient. Therefore, the above statistical methods could not be applied.