COAPTECH

A single-center, feasibility study to evaluate the use and safety of the Percutaneous Ultrasound Gastrostomy technique

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Statistical Analysis Plan

The primary objective of the proposed study is thus the demonstration of safety and feasibility of a novel gastrostomy tube placement (PUG) method using the PUMA-G device in this first-in-human pilot study (n=25). A sample size of 25 was chosen for this study because it provides 80% chance of seeing at least one serious-device related event assuming the event rate is at least 6.3% and a 90% chance of seeing at least one event if the true event rate is at least 11.3%. If no events are observed, then the 95% two-sided upper bound exact binomial CI for the event rate is 13.7%. Hence, the planned sample size has both power to detect at least one event should the event rate be consistent with literature estimates and is sufficient to obtain an upper bound on the event rate of less than 15%; so the planned sample size is considered adequate for this feasibility study. See Table 1 below for calculations.

Table 1: Sample size calculations to optimize ability to detect PUG adverse event

Sample Size	Provides 80% to detect at least one study adverse event if the actual adverse event rate is:	Provides 90% to detect at least one study adverse event if the actual adverse event rate is:	95% One-sided Upper bound for Safety Event Rate	95% Two-sided Upper bound for Safety Event Rate
25	6.3%	8.8%	11.3%	13.7%

It is acknowledged that as a feasibility study, the proposed clinical evaluation is not powered to demonstrate a difference in adverse event outcomes when compared to the standard of care, radiologic gastrostomy tube placement method. In part, this is due to the relatively low rate of complications placement (~4% complication rate). Sample sizes numbering in the thousands would be necessary. These infeasible sample sizes at this stage highlight the need to initially evaluate the PUMA-G device in a feasibility study, per standard development of most medical devices. If successful, further powered studies will be warranted.