Safety and Effectiveness of A Novel Enteral Feeding System: Prospective Study - Statistical Analysis Plan (NCT06173063)

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1.0 Purpose

The purpose of this document is to record the sample size, scoring ratings and statistical methods applied to the Mobility+ Post-Market Clinical Study.

It also captures the supplemental baseline and outcome data recorded during the study.

2.0 Reference Documents

Document Type	Document Description
CLP001	Mobility+ Post-Market Clinical Study Protocol

3.0 Sample size

The aim was to recruit 25 participants, to allow for potential dropouts and obtain data for an ideal minimum of 20 participants. The number of patients who were screened was high, at 548. Of this 548, a high proportion (n= 493, 90%) were excluded as they did not meet the study criteria. Furthermore, 11 declined to take part, 25 did not take part for other reasons (e.g. did not show up to appointment or their clinical plan included intent to taper down enteral nutrition (EN) intake), resulting in 19 being the number of participants included. This was the highest number feasible to include in the time frame of the screening and close to the ideal minimum of 20 participants.

4.0 Scoring ratings

A score was given for each rating from 1 to 5, with 5 being the most positive response.
The scoring systems applied were as outlined below:

Patient perspectives on mobility (using current system vs. Mobility+)	Very easy (5) Easy (4) Neutral (3) Difficult (2) Very difficult (1).
Patient perspectives on ease of use	Strongly agree (5) Somewhat agree (4) Neutral (3) Somewhat disagree (2) Strongly disagree (1).
Participant perspective on Quality of life	Excellent (5) Good (4) Neutral (3) Bad (2) Very bad (1)

An overall score for each measure was calculated and averaged for the cohort.

5.0 Statistical test applied

The statistical test used was a paired T-test with ANOVA. Statistical significance was set at P <0.05. Analyses were performed with IBM SPSS Statistics for Windows, version 29.0.1 (IBM Corp., Armonk, N.Y., USA).

6.0 Supplemental Baseline data gathered

The following supplemental Baseline Data was gathered at patient enrollment (n=17).

Variables	
Diagnosis, *n* (%)	
Malignancy	13 (76.5)
GI Dysmotility	2 (11.8)
Bariatric Surgery	1 (5.9)
Functional Disorder	1 (5.9)
Occupation, *n* (%)	
Working/studying	6 (35.3)
Not working/studying	11 (64.7)
Type of Feeding Tube, *n* (%)	
G-Tube	14 (82.4)
J-Tube	3 (17.6)
Type of Feeding System before study, *n* (%)	
Infusion Pump	4 (23.5)
Bolus/Syringe	3 (17.6)
Gravity	7 (41.2)
Combination*	3 (17.6)
Daytime or Night-time Feeds n (%)	
Daytime Only	10 (58.8)
Nighttime Only	1 (5.9)
Both Day & Night-time	6 (35.3)

*Combination was Bolus/syringe, Gravity.

7.0 Supplemental Outcome data gathered

The following supplemental Outcome Data was gathered (n=17).

Compliance and Effectiveness (n (%))	
Successfully and safely feed with Mobility+	17 (100)
Achieved use of Mobility+ for minimum 2 daily EN feeds	16 (94.1)

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