

Supplemental Digital Content 4, eTable 2. Clinical Outcomes for Patients Enrolled within 48 hrs of ICU Admission By Enteral Nutrition Group

| Clinical Outcomes | Early EN (n = 213) | No early EN (n = 186) | Estimate (95% CI) ^a | p ^b |
|--|-----------------------|--------------------------|-------------------------------------|-------------------|
| 90-day hospital mortality, n (%) | 17 (8) | 28 (15) | OR=0.64 (0.32-1.27) | 0.20 |
| 28-day hospital mortality, n (%) | 16 (8) | 22 (12) | OR=0.81 (0.40-1.62) | 0.54 |
| ICU-free days (through Day 28), median (IQR) | 21.1 (12.9-24.0) | 18.1 (3.4-23.1) | HR=1.13 (0.91-1.40) | 0.27 |
| Hospital-free days (through Day 28), median (IQR) | 11 (0-19) | 3.5 (0-14) | HR=1.41 (1.06-1.87) | 0.02 |
| Ventilator-free days (through Day 28), median (IQR) | 22.1 (15.8-25.0) | 19.8 (9.0-23.4) | HR=1.17 (0.94-1.48) | 0.16 |
| Maximum PELOD score (Day 2 through Day 28), median (IQR) | 11 (11-20) | 12 (11-21) | MD=-1.6 (-3.4-0.2) | 0.08 |
| Healthcare-associated infections, n (%) | 1 (<1) | 5 (3) | OR=0.16 ^c (0.02-1.21) | 0.08 ^c |

CI = confidence interval, EN = enteral nutrition, HR = hazard ratio, ICU = intensive care unit, IQR = interquartile range, MD = mean difference, OR = odds ratio, PELOD = pediatric logistic organ dysfunction.

^a OR < 1 indicates fewer events; HR > 1 indicates more ICU-free, hospital-free, and ventilator-free days; and MD < 0 indicates lower maximum PELOD scores for the early EN group compared to the no early EN group.

^b Effect estimates and p values comparing early EN and no early EN groups were calculated with the use of logistic, proportional hazards, or linear regression, as appropriate, adjusting for age category, BMI z-score category, mean vasopressor-inotrope score at randomization, primary reason for ICU admission and PRISM-III score at 12 hours from ICU admission accounting for site as a cluster variable.

^c Unadjusted odds ratio and p value comparing early EN and no early EN groups were calculated with the use of univariate logistic regression accounting for site as a cluster variable due to low counts.