TITLE:

Gastric Residual Volume Assessment in Critically Ill Children: The GASTRIC-PICU Randomized Clinical Trial

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Key Points

Question Is not routinely assessing gastric residual volume noninferior to regular assessment to guide enteral feeding in critically ill children?

Findings In this randomized trial of 4700 invasively ventilated children on PICU, not assessing gastric residual volume regularly was noninferior to usual care in terms of a composite of length of ventilation and mortality, but significantly increased the proportion of children reaching nutritional targets at 72 hours.

Meaning In invasively ventilated children, the routine assessment of gastric residual volume does not alter clinical outcomes and impairs enteral feeding. This routine practice should be discontinued.

Abstract

Importance Routine assessment of gastric residual volume (GRV) to guide enteral feeding in critically ill children is widespread but not based on evidence. Perceived high gastric volumes often lead to withholding feeds, impairing nutritional delivery.

Objective To evaluate the effect of not routinely assessing GRV compared with at least 6-hourly assessments in mechanically ventilated children on duration of mechanical ventilation and survival and achievement of nutritional targets.

Design, Setting, and Participants A pragmatic, multicenter, randomized, noninferiority trial in 23 pediatric intensive care units (PICUs) in the United Kingdom and one in Switzerland. Four thousand seven hundred invasively ventilated children (0-16 years) who started enteral feeding were recruited between June 29, 2023 and December 7, 2025, with 30-day follow up completed on January 6, 2026.

Interventions Children were randomized (1:1) to receive usual care (6-hourly GRV assessment) or no routine GRV assessment to guide enteral feeding. In the no assessment group, feed tolerance was assessed using only clinical signs. All other feeding practices followed local protocols.

Main Outcomes and Measures The clinical co-primary outcome (noninferiority) was a composite of survival and days free from mechanical ventilation at 30 days. The nutritional co-primary outcome (superiority) was the percentage of the child's energy requirements achieved by 72 hours.

Results Of the 4700 randomized (2352 intervention and 2348 usual care), 4460 were included in the intention-to-treat analysis (median age 8 months, interquartile

range (IQR) 1-44, 42.6% female). No routine assessment of GRV was noninferior to regular 6-hourly assessments for survival and days free from mechanical ventilation at 30 days (median 25, IQR 21-27 in both groups; adjusted OR 0.95, 95% CI 0.86 to 1.05). The per protocol analysis was consistent (adjusted OR 1.01, 95% CI 0.90 to 1.13). The mean percentage of energy requirements achieved by 72 hours was 80.3% in the no routine GRV assessment group and 76.8% in the usual care group (adjusted mean difference 3.2 percentage points, 95% CI 1.3 to 5.2; *P*<.001).

Conclusions and Relevance Among critically ill children being enterally fed, not assessing GRV routinely was noninferior to regular 6-hourly measurements and significantly increased nutritional achievement at 72 hours.

Trial Registration: ISRCTN79668198

Introduction

Adequate nutrition is a priority in critical illness.[1] However, critically ill children, on average, receive less than half of their predicted energy requirements.[2,3] Withholding of feed, based on perceived risks of ventilator associated pneumonia (VAP) and necrotizing enterocolitis (NEC) [4], contributes to this nutritional deficit. Routine assessment of gastric residual volume (GRV), by measuring the volume of fluid obtained by aspirating the gastric tube, is performed in almost all UK PICUs [5] and variably globally to predict tolerance of enteral feeding. Almost always the response to a perceived 'high GRV' is to withhold feeds for a period of time. However, aspirate volume poorly reflects true GRV [6] and aspirate volume thresholds used to predict feed tolerance are both variable and poorly evidenced.[4,5]

A randomized clinical trial (RCT) in critically ill adults showed not assessing GRV had no impact on VAP but facilitated delivery of nutrition.[7] Systematic reviews have supported these findings.[8] In critically ill children, one small observational study questions the value of GRV assessment,[9] but there have been no RCTs. There is greater potential for benefit of not assessing GRV in children due to lower energy reserves and higher metabolic demands compared with adults.[10] Fear of vomiting and aspiration has been identified as the main reason for routinely assessing GRV in critically ill children.[11] Following a feasibility study,[4] we conducted the GASTRIC-PICU trial [12] to evaluate whether not routinely assessing GRV to guide enteral feeding was both noninferior in terms of a composite outcome of survival and days free from mechanical ventilation at 30 days and increases the percentage of children who achieve their estimated energy requirements by 72 hours when compared with usual care.

Methods

Trial design and oversight

The GASTRIC-PICU RCT was a pragmatic, unblinded, multicenter, parallel-group, noninferiority trial. The study protocol was approved by London–Bloomsbury Research Ethics Committee on May 10, 2023 (reference number 23/LO/0284) and was published prior to completion of the trial.[12] The trial was registered at the United Kingdom (UK) clinical study registry (https://www.isrctn.com; reference 79668198) and the Swiss National Clinical trial Portal (SNCTP000006200).

The UK National Institute for Health and Care Research (NIHR) Health Technology Assessment program funded the trial; independent data monitoring and trial steering committees were appointed. A planned interim analysis was conducted at 50% of the target sample size. The trial was sponsored and managed by the Intensive Care National Audit and Research Centre (ICNARC) clinical trials unit.

Sites and participants

The trial was conducted at 24 sites, comprising of 23 pediatric intensive care units (PICUs) in the UK National Health Service (NHS) and one in Switzerland. Children aged from 0 (>37 weeks gestational age) up to 16 years admitted to participating PICUs were included if they were enterally fed via the gastric route and invasively ventilated. Exclusion criteria included if there was an end-of-life plan in place or death was perceived as imminent, on long term ventilation via a tracheostomy, gut pathology contraindicating enteral feeding or not being fed via the gastric route (eTable 1 in Supplement 2).

Randomization

Randomization was conducted using a concealed centralized web-based system based on a computer-generated randomization sequence and was stratified by site, age, and reason for admission. Children were randomized in a 1:1 ratio to no routine GRV assessment or usual care within 24 hours of meeting all the inclusion criteria. As most UK PICUs initiated enteral nutrition early in the PICU admission,[4] a 'research without prior consent' approach was approved. [13,14] Parents or legal guardians were approached for consent as soon as possible after randomization. If the parent or guardian refused consent, approvals allowed safety and primary outcome data to be collected along with data collected up to that point being retained unless the parent or guardian requested removal of all data. The full consent process is outlined in Supplement 1.

Trial interventions

Following randomization, treatment started immediately. For patients in the no routine GRV assessment group, staff were required to not routinely assess GRV,

using only clinical signs to evaluate feeding intolerance (eFigure 1 in Supplement 2). Staff were allowed to assess GRV in justifiable clinical situations, such as prior to a procedure, vomiting or in response to clinical deterioration. For patients in the usual care group, staff were required to follow their standard local PICU practice, which included routine GRV assessments taken at least every 6 hours to guide enteral feeding. All other feeding practices followed local protocols and practices.

Study outcomes

The co-primary outcomes were a composite outcome of survival and days free from mechanical ventilation at 30 days (noninferiority) and the percentage of the child's estimated energy requirements achieved by 72 hours (superiority). Secondary outcomes were: time to achievement of target energy requirement; time to achievement of target protein requirement; diagnosis of VAP; diagnosis of NEC in infants (less than 12 months of age); duration of time with no enteral feed in the first 7 days; incidence of vomiting leading to feed stoppage in the first 7 days; documented healthcare acquired infections; and length of PICU stay. The longer-term outcomes at six months and integrated economic evaluation will be reported separately. The detailed definitions of all outcomes can be found in Supplement 1.

Sample size calculation

For the clinical co-primary outcome, a noninferiority margin of an upper limit for the odds ratio (OR) of 1.2 was selected. This corresponded to a 0.8% absolute increase in mortality and a 12-hour difference in median duration of ventilation. For 90% power to detect noninferiority, based on the upper limit of a two-sided 95% confidence intervals (CI) excluding this margin, and using an outcome distribution from the UK SANDWICH trial (4.2% mortality and log-normal distribution for duration of ventilation with median 2.9 days and lower quartile 1.0 day) [15] required a sample

size of 4000. To retain power for a per protocol (PP) analysis and allow for crossover of 10% and withdrawal of 5%, we set a total target size of 4700. The nutritional co-primary outcome was anticipated to be approximately normally distributed, with standard deviations (SD) within each group of between 20% and 40% [9]. However, because of this uncertainty in the standard deviation (SD), a blinded sample size re-estimation was undertaken at the interim analysis, according to a pre-specified statistical analysis plan. The sample size in the intention-to-treat (ITT) population required to provide 90% power at a *P* value of less than 0.05, two-sided to detect a 4% absolute difference in energy intake based on the observed pooled SD was 2258. This effect size was chosen to detect a small (Cohen's d 0.2) to very small (Cohen's d 0.1) effect based on the anticipated range of the SD.

Statistical analysis

The clinical co-primary outcome was analyzed using a proportional odds logistic regression model, with death during the first 30 days following randomization ranked as the worst outcome and surviving patients assigned values according to their total calendar days free from mechanical ventilation during the first 30 calendar days following randomization. The model was adjusted for the stratification variables, which were selected a priori based on their established relationship with outcome for critically ill children. Multiple imputation was not required for any of the baseline variables due to the high completeness. The primary effect estimate is the adjusted OR, which was calculated in both the ITT and PP populations with two-sided 95% CIs. Noninferiority will be declared if the upper limit of the CI is not more than 1.2 in both the ITT and PP populations. Secondary analyses tested the same outcome for superiority and inferiority. The two separate components of the composite clinical co-primary outcome are reported by group. The nutritional co-primary outcome was

analyzed using a linear regression model adjusted for the same baseline variables as the clinical co-primary outcome. The primary effect estimate is the difference in mean percentage of target achieved between the groups in the ITT population, which was tested for superiority and reported with a two-sided 95% CI. Both co-primary outcomes are reported in two clinically relevant subgroups: reason for admission (cardiac, respiratory, other) and PIM-3 score at admission. All secondary outcomes are reported in both the ITT and PP populations unless otherwise specified. Time-to-event outcomes were analyzed using Cox proportional hazards regression. Patients who did not achieve nutritional targets were censored at death, discharge from PICU or day 7 following randomization (whichever is earlier). Binary endpoints were compared using adjusted logistic regression. The diagnosis of VAP is reported as a rate per 1000 hours of ventilation and was analyzed using Poisson regression. Continuous endpoints were analyzed using adjusted linear regression. The feeding component of Functional Status Score was analyzed as an ordinal endpoint using adjusted proportional odds logistic regression. Ethnic origin was collected to ensure inclusivity of the research, using documentation in the child's medical records defined according to standard NHS ethnic categories.

Statistical analyses were conducted in Stata/MP version 18.0 (StataCorp).

Results

Sites and Participants

Between June 29, 2023 and December 7, 2025, a total of 17 441 critically ill children receiving invasive mechanical ventilation were screened at 23 sites, of whom 5982 were potentially eligible and 4700 were randomized (Figure 1 and eFigure 2 in Supplement 2). There were 159 patients (3.4%) who requested removal of all data,

18 patients (0.4%) not approached for consent and 63 patients (1.3%) with missing outcome data, leaving 4460 (2220 no routine GRV assessment group, 2240 usual care group) in the clinical co-primary outcome analysis (eTable 2 in Supplement 2). Data collection for the nutritional co-primary outcome analysis stopped on February 19, 2025 following a pre-specified blinded sample size re-estimation, which indicated sufficient sample size. An additional 188 (4.0%) parents refused or withdrew consent or opted out of their child's data collection leaving 2936 (1424 no routine GRV assessment group, 1512 usual care group) in the analysis of the nutritional co-primary outcome. Patients whose parents had that refused or withdrew consent were also excluded from analyses of secondary outcomes. Thirty day follow up was completed on January 6, 2026.

Patient baseline characteristics were similar between the two groups (Table 1). Over half of patients were aged <1 year, with a median age of 8 months in each group. The majority of patients were male (57.2%), were feeding or eating normally prior to randomization (80.6%) and were admitted for a non-cardiac reason (78.7%). Patients were representative of the population admitted to PICUs in the UK. [16] The majority of patients received continuous enteral feeding as their initial mode of feeding (eTable 3 in Supplement 2).

GRV assessments

A total of 48,516 GRV assessments were performed in 2,208 patients, equating to 3.8 assessments per 24 hours, in the usual care group. In the no routine GRV assessment group, 5,903 GRV assessments were performed in 1,267 patients, equating to 0.5 assessments per 24 hours (eTable 4 in Supplement 2). Adherence was monitored in the first four charting days following randomization. In-line with the protocol, 363 (16.1%) patients in the no routine GRV assessment group had one or

more GRV assessments for specified clinical reasons. In addition, 357 (15.9%) patients in the no routine GRV assessment group had one or more GRV assessments for reasons not specified in the protocol or, most commonly, for an unknown or undocumented reason. In the usual care group, 29 (1.3%) patients had one or more calendar days with no GRV assessment (eTable 5 in Supplement 2). In the no routine GRV assessment group, 80 (4.0%) patients had their feed stopped due to the GRV assessment compared to 406 (19.3%) in the usual care group (eTable 6 in Supplement 2).

Primary and secondary outcomes

Survival and days free of mechanical ventilation at 30 days had a median of 25 (IQR, 21, 27) in both groups (adjusted OR 0.95, 95% CI 0.86 to 1.05; Table 2 and Figure 2 and eTable 7 and eTable 8 in Supplement 2). The upper bound of the 95% CI fell within the pre-specified noninferiority margin of 1.2 (P<.001) confirming the noninferiority of the intervention. Similar results were seen in the per protocol analysis (adjusted OR 1.01, 95% CI 0.90 to 1.13; P=.001). The mean percentage of estimated energy requirements by 72 hours after randomization was 80.3% in the no routine GRV assessment group, and 76.8% in the usual care group (adjusted mean difference 3.2 percentage points, 95% CI 1.3 to 5.2; P<.001).

The duration of time with no enteral feed in the first 7 days was significantly lower in the no routine GRV assessment group (adjusted mean difference −1.7 hours, 95% CI −3.1 to −0.4; P<.001). There were no significant differences between the two groups for any of the other secondary outcomes including incidence of vomiting leading to feed stoppage in the first 7 days (adjusted OR 1.16, 95% CI 0.94 to 1.43; P=.17), time to achievement of target calories (adjusted HR 1.01, 95% CI 0.91 to 1.12; P=.86), or time to achievement of target protein (adjusted HR 1.03, 95% CI

0.90 to 1.17; *P*=.68). The diagnosis of NEC was no different between the groups (2.6% vs 2.5%; adjusted OR 1.05, 95% CI 0.63 to 1.76; *P*=.85). Diagnosis of VAP was similar in the no routine GRV assessment group (6.0% vs 5.4%), and not significantly different (adjusted OR 1.12, 95% CI 0.85 to 1.47; *P*=.42). Secondary outcomes were consistent in the per protocol population (eTable 9 in Supplement 2). Three serious adverse events were reported, two (ischaemic colitis; transverse colon perforation) in the no routine GRV assessment group and one (caecal perforation) in the usual care group.

There was no evidence of heterogeneity by reason for admission and PIM-3 score at admission for both co-primary outcomes (Figure 3).

Discussion

Amongst invasively ventilated children admitted to UK PICUs, not routinely assessing GRV did not worsen the composite outcome of survival and days free of mechanical ventilation compared with usual care. In addition, omitting this practice significantly increased the percentage of the child's estimated energy requirements achieved by 72 hours. Although this effect was small, any improvements to reduce cumulative energy deficits are believed to be beneficial.

There was no clinically significant harm associated with not routinely assessing GRV detected. This included areas of prior concern including diagnosis of VAP and NEC. These findings support widespread de-implementation of the practice of routine GRV assessment in critically ill children. However, there remain justifiable reasons to assess GRV based on clinical assessment. Our results are consistent with a previous multicenter trial in critically ill adults [7], single center trials in preterm neonates [17,18], and observational data in children [9]. A multicenter noninferiority

trial in 452 adults showed no increase in VAP when GRV was not assessed alongside significantly greater nutritional attainment [7]. Two single center trials involving 258 preterm neonates showed no harm when GRV was not assessed but did not detect a change in the time to achieve full feeds [17] although weight gain and overall nutritional delivery were improved [18]. A large, international trial (neoGASTRIC) [19] is currently assessing the risks and benefits of routine GRV assessment in 7040 preterm neonates; recruitment is completed and results are expected in late 2026.

The strengths of our trial include both the total number of patients recruited (the largest individually randomized trial undertaken in PICU) and the representativeness of this population to the UK population of critically ill children. The trial was performed in 22 of the 27 UK PICUs and one in Switzerland, and a high proportion of eligible patients were randomized. As with other recent trials, the research without prior consent model facilitated this inclusiveness [20,21]. The endpoints were selected with extensive consultation with professionals and patients and families as being of direct relevance to their experience of PICU. The duration of ventilation and 30-day mortality in the usual care group were similar to the pre-trial estimates. The sample size was sufficient to exclude an 0.8% absolute change in mortality and a 12-hour difference in median duration of ventilation. The sample size required to determine noninferiority of this outcome meant we had sufficient power to capture the impact on delivery of nutrition. Adherence was high, leading to a high separation between the groups in terms of GRV assessments.

One limitation of our study is the presence of post-randomization exclusions. This has been seen in some of our previous pragmatic trials and is likely linked to the use of the research without prior consent approach. While the total numbers were small

in comparison with the trial population, the fact that consent was declined more frequently in the intervention than control arms should be noted. As a mitigation for this, our ethical approvals allowed us to include primary outcome and safety data for non-consented children. Secondly, as an unblinded study, there was potential for bias from the bedside nurses' threshold for non-routine aspirations of gastric tubes varying. While the adherence data suggests this was not common, we cannot exclude the possibility that staff chose to aspirate to confirm the nasogastric tube position at different thresholds in the no routine GRV assessment group. Finally, we only included children who were invasively ventilated, and future randomized trials should examine whether GRV assessment is helpful for those on non-invasive respiratory support.

These results, alongside similar findings in adult trials, might arise either from the true GRV not predicting risk and benefits of enteral feeding effectively, or from the volume that can be aspirated via a gastric tube being an insufficiently precise measure of that true volume.

Conclusion

Amongst critically ill children receiving mechanical ventilation in PICU, routine GRV assessments used to guide enteral feeding do not improve outcomes and reduce the achievement of nutritional goals. This practice should be stopped and only undertaken for specific clinical indications

Figure Legends/footnotes

Figure 1. Screening, randomization and data completeness

ITT Intention to treat population; PP Per Protocol population

[a] Did not meet inclusion criteria: Aged <37 weeks corrected gestational age or aged ≥ 16 years (N=443); Extubation planned in next 48 hours (N=6,857); No intention to start feeding via the gastric route (N=6,182). Note patients may not meet > 1 inclusion criteria

[b] Met exclusion criteria: Post pyloric feeding or jejunostomy (N=171); End-of-life care plan in place (N=127); On long term invasive mechanical ventilation (N=262); Current or recent gut pathology or surgery (N=452); Known to have been enrolled in the GASTRIC-PICU trial in the last 6 months (N=346). Note patients may meet > 1 exclusion criteria

[c] Excludes 90 patients randomised in error (duplicate randomisations/previously randomised to GASTRIC

[d] Date of blinded sample size re-estimation where nutritional data collection was stopped

Figure 2: Distribution of the clinical co-primary outcome of survival and days free of mechanical ventilation at 30 days

(A) shows the cumulative proportion of patients in each treatment group with each value of number of days of mechanical ventilation during the first 30 days following randomization, with death listed first on the axis, corresponding to a value of -1. Curves that rise more steeply indicate a less favorable distribution in the number of days of mechanical ventilation. (B) shows the distribution of days of mechanical ventilation or death as horizontally stacked proportions for each treatment group. Blue represents worse outcomes and yellow represents better

Figure 3: Subgroup analyses of the co-primary outcomes

(A) shows subgroup analyses of the clinical co-primary outcome (survival and days free of mechanical ventilation up to 30 days). Odds ratios below 1 favour the no routine GRV assessment group. The line at OR=1.2 indicates the non-inferiority margin used in the trial. Where the upper limit of the 95% CI does not cross the NI margin line, no routine GRV assessment is deemed non-inferior ; (B) shows subgroup analyses of the nutritional co-primary outcome (percentage of nutrition achieved by 72 hours). Mean differences above 0 favour the no routine GRV assessment group.

Analyses were adjusted for main reason for admission to PICU, age group at randomisation and site as a random effect ; Continuous interactions are illustrated using quintiles of the continuous variable

PIM-3 Paediatric Index of Mortality 3 ; NI Non-inferiority

[a] Odds ratio from proportional odds logistic regression ; [b] Mean difference from linear regression model

397 **Table 1: Baseline characteristics**
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Characteristics	No routine GRV assessment N=2256	Usual care N=2267
Age group[a], n/N (%)		
<1 month	417/2256 (18.5)	423/2268 (18.7)
≥1 month to <12 months	892/2256 (39.5)	899/2268 (39.6)
≥12 months	947/2256 (42.0)	946/2268 (41.7)
Age (months)[b]		
Mean (SD) [N]	34.1 (52.6) [2253]	34.0 (51.7) [2261]
Median (IQR)	8 (1, 43)	8 (1, 45)
Sex[b], n/N (%)		
Female	950/2253 (42.2)	975/2261 (43.1)
Male	1303/2253 (57.8)	1286/2261 (56.9)
Ethnicity[c,d], n/N (%)		
White	1076/1877 (57.3)	1139/1983 (57.4)
Multiethnic	71/1877 (3.8)	87/1983 (4.4)
Asian	260/1877 (13.9)	296/1983 (14.9)
Black	113/1877 (6.0)	125/1983 (6.3)
Other	71/1877 (3.8)	57/1983 (2.9)
Not stated	286/1877 (15.2)	279/1983 (14.1)
Quintile of index of multiple deprivation (IMD)[c, e], n/N (%)		
1 (least deprived)	210/1567 (13.4)	217/1652 (13.1)
2	254/1567 (16.2)	291/1652 (17.6)
3	307/1567 (19.6)	304/1652 (18.4)
4	374/1567 (23.9)	415/1652 (25.1)
5 (most deprived)	422/1567 (26.9)	425/1652 (25.7)
Weight (kg)[b]		
Mean (SD) [N]	13.8 (16.6) [2253]	13.5 (15.6) [2261]
Median (IQR)	8 (4, 15)	8 (4, 15)
Child feeds normally prior to randomization[b], n/N (%)	1814/2239 (81.0)	1831/2252 (81.3)
Intended feeding route[b], n/N (%)		
Gastric tube	2113/2247 (94.0)	2092/2254 (92.8)
Gastrostomy	134/2247 (6.0)	162/2254 (7.2)
Cardiac reason for admission[a], n/N (%)	474/2256 (21.0)	490/2268 (21.6)
PIM-3 score at admission (%)[c, f]		
Mean (SD) [N]	4.6 (7.9) [1880]	4.7 (8.9) [1984]
Median (IQR)	1 (1, 5)	2 (1, 5)
Planned admission[c], n/N (%)	373/1823 (20.5)	424/1891 (22.4)
Length of PICU stay prior to randomization (hours)[b]		
Median (IQR)	18 (8, 37)	18 (8, 36)

Length of ventilation prior to randomization (hours)[b]		
Median (IQR)	19 (10, 34)	20 (10, 35)

[a] From randomization system; [b] From eCRF; [c] From PICANet linkage; [d] Child's ethnic origin as recorded in the medical records defined according to standard NHS ethnic categories and codes and Ethnic Category 2021 categories; [e] IMD Index of Multiple Deprivation is an index of relative deprivation based on postcode. IMD is reported by quintiles, with a lower quintile indicating less deprivation; f PIM-3 is an index of mortality predicting the risk of mortality at admission to PICU. The index score ranges from 0-100%, with a lower score indicating a lower probability of mortality.
SD Standard deviation; IQR Interquartile range

Table 2: Primary and Secondary Outcomes

	No routine GRV assessment	Usual care		Absolute difference	Effect estimate	*P* value
Co-primary outcomes						
Survival and days free of mechanical ventilation, median (IQR) [N]	25 (21, 27) [2220]	25 (21, 27) [2240]	ITT	-	OR=0.95 (0.86, 1.05)	<.001[a]
	26 (22, 27) [1657]	26 (22, 27) [2071]	PP	-	OR=1.01 (0.90, 1.13)	.001[a]
			CACE	-	OR=0.99 (0.89, 1.10)	<.001[a]
Percentage of nutrition achieved by 72 hours, mean (SD) [N]	80.3 (28.2) [1424]	76.8 (30.5) [1512]	ITT	-	MD=3.24 (1.29, 5.19)	<.001
	81.1 (27.7) [1189]	77.0 (30.5) [1482]	PP	-	MD=3.34 (1.30, 5.39)	<.001
			CACE	-	MD=3.90 (1.55, 6.25)	<.001
Secondary outcomes at Day 8 (ITT)						
Incidence of vomiting leading to feed stoppage, n/N (%)	204/1992 (10.2)	190/2105 (9.0)		RD=1.2 (-0.5, 3.0)	OR=1.16 (0.94, 1.43)	.17
Time (days) to achievement of target calories, median (IQR)	6.0 (5.0, 6.0) [1417]	6.0 (5.0, 6.0) [1518]		RD[b]=1.2 (-0.5, 3.0)	HR=1.01 (0.91, 1.12)	.86
Time (days) to achievement of target protein	- [c] [1416]	- [c] [1518]		RD[b]=1.2 (-0.5, 3.0)	HR=1.03 (0.90, 1.17)	.68
Duration of time with no enteral feed (hours)	20.7 (21.7) [1992]	22.7 (23.5) [2105]		-	MD=-1.7 (-3.1, -0.4)	<.001
Secondary outcomes at PICU discharge (capped at 30 days) (ITT*)						
Diagnosis of Necrotizing Enterocolitis (NEC)	30/1158 (2.6)	31/1228 (2.5)		RD=0.1 (-1.1, 1.3)	OR=1.05 (0.63, 1.76)	.85
Diagnosis of ventilator acquired pneumonia	120/2007 (6.0)	114/2128 (5.4)		RD=0.6 (-0.8, 1.9)	OR=1.12 (0.85, 1.47)	.42

VAP, rate per 1000 hours of ventilation	0.37	0.34	-	IRR=1.09 (0.84, 1.41)	.52
Other documented healthcare acquired infections	222/2007 (11.0)	252/2128 (11.8)	RD=-0.7 (-2.5, 1.2)	OR=0.93 (0.76, 1.13)	.47
Secondary outcomes at discharge (ITT)					
Length of PICU stay, median (IQR) [N]					
Survivors	5 (3, 11) [1922]	5 (3, 10) [2038]	-	PI=0.50 (0.48, 0.52)	.79
Non-survivors	14 (5, 36) [86]	11 (4, 24) [87]	-	PI=0.42 (0.34, 0.51)	.08
Length of hospital stay, median (IQR) [N]					
Survivors	13 (7, 28) [1853]	13 (7, 26) [1953]	-	PI=0.50 (0.48, 0.52) [c]	.86
Non-survivors	17 (6, 63) [99]	15 (5, 37) [109]	-	PI=0.46 (0.38, 0.54) [c]	.35

Analyses are adjusted for stratification variables, except for analyses of length of PICU stay and length of hospital stay which are unadjusted.

[a] Based on noninferiority margin of 1.2; [b] Risk difference at 8 days post-randomisation; [c] < 50% patients achieved target protein

OR Odds Ratio; MD Mean difference; HR Hazards Ratio; IRR Incidence Rate Ratio; RD Risk difference; PI probabilistic index from Wilcoxon rank-sum test; IQR Interquartile range; SD Standard Deviation; ITT Intention-to-treat; PP per protocol; CACE Complier average causal effect; VAP Ventilator acquired pneumonia

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