Abbott Nutrition Product Studies in the ICU

CITATION	STUDY OVERVIEW	CONCLUSION
Seres, DS, et al. Pilot study of a peptide-based enteral formula versus a polymeric enteral formula in critically ill patients. A.S.P.E.N Clinical Nutrition Week 2015, accepted poster presentation.	A pilot study of 49 ICU patients with an APACHE II score ≤24 and required enteral nutrition to assess the safety and GI tolerance of a peptide-based enteral formula (Vital AF 1.2 Cal®) to a standard polymeric enteral formula (Osmolite® 1.2 Cal).	Compared to the control, the peptide-based enteral nutrition (Vital AF 1.2 Cal) was safe, well tolerated, and resulted in: • Fewer days of GI complications (4.29 vs 7.13 days, *P*=0.0489) • Fewer days of distention (0.88 vs 2.29 days, *P*=0.0243)
Painter TJ, et al. Immune-enhancing nutrition improves nutrition measures and infection rates in traumatically brain-injured patients. Paper presented at: Clinical Nutrition Week; February 9-12, 2013; Phoenix, Arizona.	Retrospective review of prospectively collected data in trauma patients with an isolated moderate to severe traumatic brain injury (TBI). The objective of the study was to determine if immune-enhancing nutrition (IEN) (Pivot® 1.5 Cal) decreased the rate of nosocomial infections in the moderate to severe TBI patient in comparison to those who received a standard nutrition formula (SF) (TwoCal® HN). Charts were reviewed for: • Prealbumin data from start of tube feedings to stop of feedings • Infection data (ie, pneumonia, bacteremia, urinary tract infection [UTI]) up to one month from start of tube feedings; total hospital days • ICU days, and ventilator days in each group	A total of 180 patients with TBI met inclusion criteria and received either Pivot (n=85), or a standard formula (SF) (n=95). Patients receiving Pivot had significantly higher prealbumin levels at the second, third, and fourth week of admission compared to the SF group: • 22.1 versus 17.3 at 2 weeks (*P*=0.01) • 25.1 versus 19.6 at 3 weeks (*P*=0.04) • 27.8 versus 18.8 at 4 weeks (*P*=0.009) Patients receiving Pivot were found to have lower rates of bloodstream infections (bacteremia) and similar rates of urinary tract infections and pneumonias compared to the SF group.
Bedi NM MS, et al. Use of an immune modulating enteral formula in post-operative cardiac surgery patients is associated with fewer infectious complications and decreased hospital length of stay. *JPEN J Parenter Enteral Nutr.* 2011;35(1):138.	Non-randomized, prospective, historical control study that evaluated the impact of an immune-modulating enteral formula (Pivot 1.5 Cal) on patients (n=172) who required tube feeding following cardiac surgery between 3/08-6/10. These data were compared to data from the historical cohort (n=265) recorded between 10/04—3/08 that received standard enteral formulas with no added arginine or fish oils.	Post-operative length of stay was significantly shorter in the immune-modulating formula group compared to the controls (median 27 days vs 31 days, *P*=0.002). The overall incidence of infectious complications was also less in the immune-modulating formula group (18% vs 26.4%, *P*=0.048). Additionally, there were significant differences between the groups in the development of sepsis and *C. difficile* infection in favor of the immune-modulating formula group.

Infection type	Pivot (n=95)	SF (n=95)	*P* value
Bacteremia	11.8%	22.8%	<0.05
Urinary tract (n)	22.4% (19)	23.2% (22)	NS
Pneumonia (n)	63.5% (54)	56.8% (54)	NS

NS=not significant

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Clinical Summary Overview

CITATION

Pontes-Arruda A, et al. Enteral nutrition with eicosapentaenoic acid, γ-linolenic acid and antioxidants in the early treatment of sepsis: results from a multicenter, prospective, randomized, double-blinded, controlled study: the INTERSEPT Study. *Crit Care.* 2011;15(3):R144.

STUDY OVERVIEW

This investigator-initiated, prospective, multicenter, randomized, double-blinded, controlled trial was conducted to evaluate the effect of feeding Oxepa® versus an isonitrogenous, isocaloric control formula (Ensure Plus HN®) in delaying the progression of the disease to severe sepsis and/or septic shock in patients with early sepsis without organ failure. This is the first study to feed this type of formula to critically ill patients with early sepsis without organ failure.

CONCLUSION

Based on the intent-to-treat analysis:
Compared to patients fed the control product, patients fed Oxepa developed:
- Less severe sepsis (sepsis associated with at least one organ failure) or septic shock (sepsis associated with hypotension despite adequate fluid resuscitation)
- Fewer cardiovascular and respiratory failures

Compared to patients fed the control product, patients fed Oxepa experienced:
- More ICU-free days
- More hospital-free days
- And fewer required mechanical ventilation

	Oxepa (n=57)	Control (n=58)	*P value*
Severe sepsis (sepsis associated with at least one organ failure) or septic shock (sepsis associated with hypotension	26.3%	50%	=0.0259
Cardiovascular failure	21.0%	36.2%	=0.0381
Respiratory failure	24.6%	39.6%	=0.0362
ICU-free days, mean	21.1 ± 4.7	14.7 ± 5.1	<0.001
Hospital-free days, mean	19.5 ± 7.8	10.3 ± 8.6	<0.001
Required mechanical ventilation	18.9%	33.9%	=0.295

No difference was observed in 28-day all-cause mortality (26.2% in the Oxepa group vs 27.6% in the control group, *P*=0.72).

Pontes-Arruda A, et al. The use of an inflammation-modulating diet in patients with acute lung injury or acute respiratory distress syndrome: a meta-analysis of outcome data. *JPEN J Parenter Enteral Nutr.* 2008;32:596-605.

This meta-analysis was conducted with pooled data from 3 published, randomized, controlled studies evaluating the outcomes of an inflammation-modulating diet enriched with eicosapenaenoic acid (EPA), gamma-linolenic acid (GLA), and elevated antioxidants (Oxepa®) vs a control diet in mechanically ventilated patients with acute lung injury (ALI)/acute respiratory distress syndrome (ARDS).

Patients fed Oxepa experienced more ventilator-free and ICU-free days compared with patients fed the control diet.

	Oxepa	Control	*P* value
28-Day ventilator-free days	17.0 ± 9.7	12.1 ± 9.9	<.0001
28-Day ICU-free days	15.1 ± 10.0	10.8 ± 9.6	<.0001

New Organ Dysfunction: Patients fed Oxepa experienced an 83% risk reduction in developing new organ failures.
28-Day All-cause Mortality: The use of Oxepa resulted in a 60% risk reduction in 28-day in-hospital all-cause mortality.

Kenler AS, et al. Early enteral feeding in postsurgical cancer patients. Fish oil structured lipid-based polymeric formula versus a standard polymeric formula. *Ann Surg.* 1996;223(3):316-333.

Prospective, randomized, controlled trial of the effects of n-3 PUFAs provided as a fish oil/MCT structured lipid in a complete enteral formula vs an isonitrogenous, isocaloric control formula was studied in 50 adult patients undergoing surgery for upper GI malignancies. All patients had a J-tube placed at time of surgery and enteral feeding was initiated within 48 hours postoperatively. Outcomes were measured at baseline and study day 7.

The study results showed that patients receiving the fish oil/MCT structured lipid formula (the same type of structured lipid found in Vital AF 1.2 Cal) experienced no negative side effects, had significant incorporation of eicosapentaenoic acid (EPA) into plasma and erythrocyte phospholipids, experienced a significant decrease in the total number of GI complications (down 40%-50%) and infections (down 54%) compared to patients receiving the control formula.

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