

SAFETY AND EFFICACY OF AN OLIVE OIL-BASED TRIPLE-CHAMBER BAG FOR PARENTERAL NUTRITION: A PROSPECTIVE, RANDOMIZED, MULTI-CENTER CLINICAL TRIAL IN CHINA.

OLIVE oil-based lipid emulsion was associated with fewer infections and was easier to use than SOYBEAN oil-based lipid emulsion in the largest parenteral nutrition [PN] study of its kind.

STUDY DESIGN

An open-label, prospective, randomized [1:1], comparative, multi-center, active-controlled, parallel-group investigational trial

- Conducted between December 2011 and November 2012 in 18 centers across China
- Patients aged ≥ 18 to ≤ 80 years old; inpatients who were hospitalized ≤ 14 days before enrollment; required PN because oral or enteral nutrition was not possible, insufficient, or contraindicated
- Treatments were administered for a minimum of 5 days up to 14 days [to achieve approximately 25 kcal/kg/day, 0.9 g/kg/day amino acids, 0.8 g/kg/day lipid]

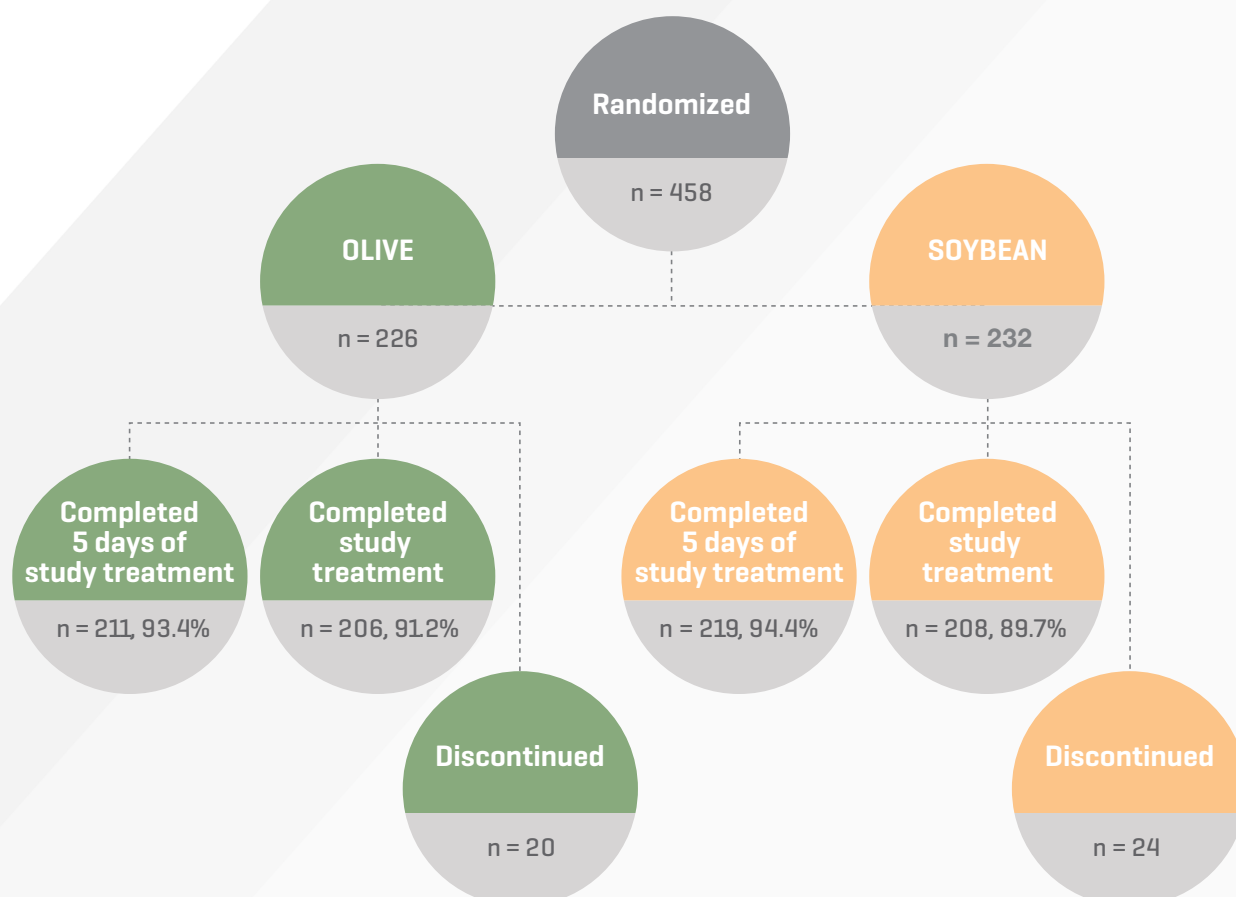
HYPOTHESES UNDERLYING THIS STUDY WERE:

- Evaluate the incidence of infections using 2 different lipid emulsions:

OLIVE: containing amino acid solution, glucose, and 10% lipid emulsion containing olive oil 80%+soybean oil 20%

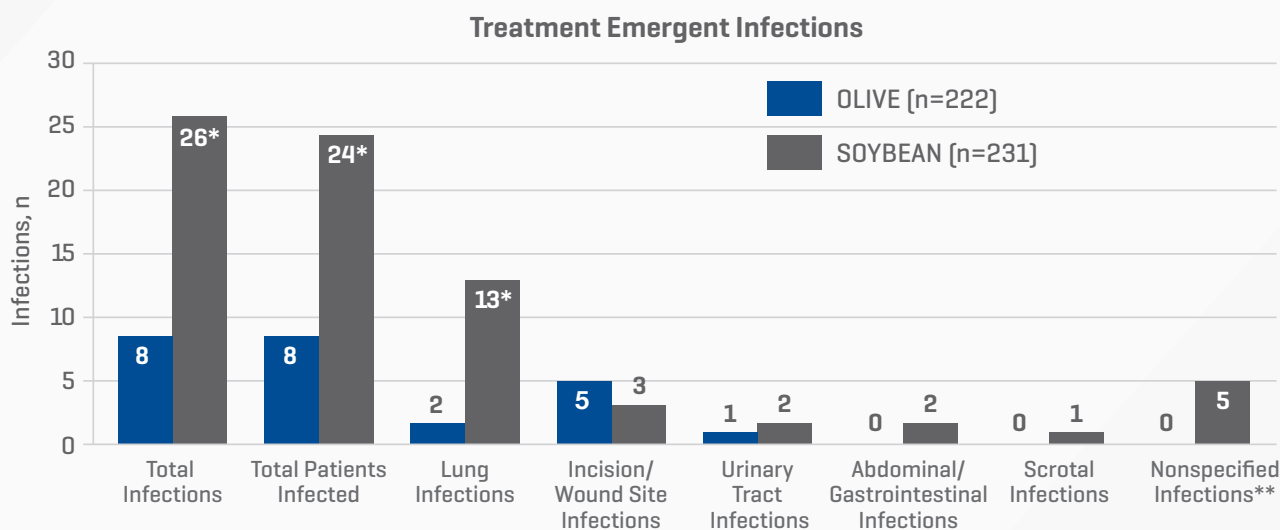
SOYBEAN: containing amino acid solution, glucose solution, and 10% lipid emulsion containing 100% soybean oil

- Assess the delivery, efficacy, and safety of an OLIVE oil-based lipid PN regimen compared with a compounded SOYBEAN oil-based lipid PN regimen in Chinese adults for whom oral or enteral nutrition was not possible, insufficient, or contraindicated.



RESULTS

In adult patients who required PN and were hospitalized for ≤14 days, the OLIVE group experienced significantly fewer infections compared to the SOYBEAN group.



*P<0.01

**Systemic infection, site not identified

- Significantly more patients experienced infections or infestations in the SOYBEAN group [10.4% [24/231]] than the OLIVE group [3.6% [8/222]]
- The most common infections were lung infections, which were higher in the SOYBEAN group

In adult patients who required PN and were hospitalized for ≤14 days, serum prealbumin levels were significantly higher in the OLIVE group compared with the SOYBEAN group at Day 5.

Prealbumin Day 5 (Mean ± SD)



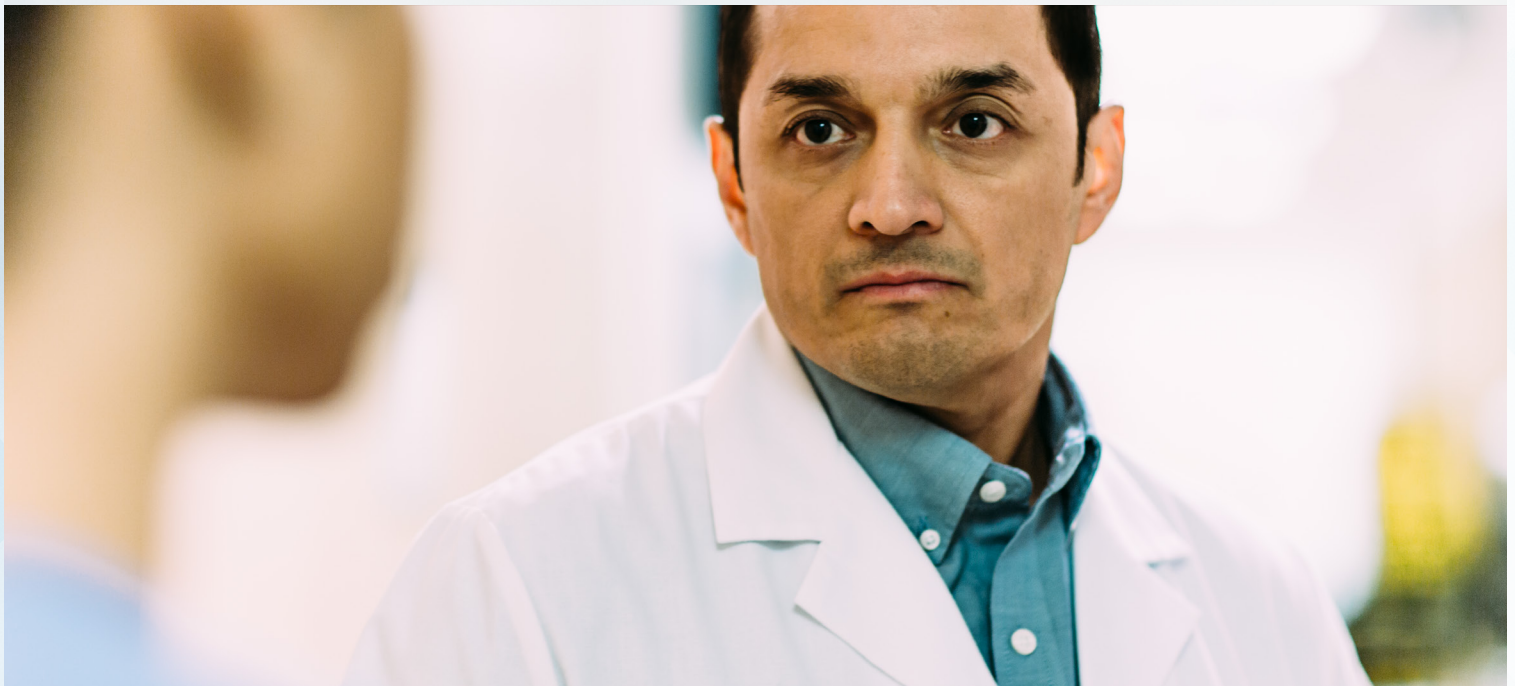
*mITT=modified intention-to-treat

[†]Least-squares geometric mean

- Olive efficacy in the modified intention-to-treat population and prespecified subgroups

In the largest prospective, randomized, open-label, controlled, multi-center study to date that compares 2 lipid emulsions:

- OLIVE oil-based PN regimen improved nutritional outcomes, was associated with fewer infections, was well tolerated, and was easier to use compared with a compounded soybean oil-based PN regimen.



Open Access Link:

<https://nutritionj.biomedcentral.com/articles/10.1186/s12937-015-0100-6>

REFERENCE

1. Jia ZY, Yang J, Xia Y, Tong DN, Zaloga GP, Qin HL. Safety and efficacy of an olive oil-based triple-chamber bag for parenteral nutrition: a prospective, randomized, multi-center clinical trial in China. *Nutr J*. 2015 Nov 14;14(1):119.

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