Reviewer's report

Title: Safety and Efficacy of an Olive Oil-based Triple-chamber Bag for Parenteral Nutrition: A Prospective, Randomized, Multicenter Clinical Trial in China

Version: 1 Date: 3 August 2015

Reviewer: Muraldihar Premkumar

Reviewer's report:

Major revisions:

Reasons to study for only 14 days of lipid infusion. As we know the effect of various TPN emulsions are more evident in prolonged exposures (3-4 weeks and beyond). The authors should point out this important deficiency.

The effect of OLIVE on liver functions and lipid studies are interesting. Particularly the effect on GGT goes unmentioned in the discussion. The author should address these in much more detail.

The minor revisions are noted below, according to the place of mention in the manuscript.

Abstract:

In the results section:

The authors should mention that it is an 'open labeled study'.

. a. The statement regarding superior LSGM of OLIVE over SOYBEAN in terms of prealbumin [LSGM] ratio [95% CI] 1.12 [1.06, 1.19]; P = 0.002), is repeated in the second sentence. This redundancy should be corrected.

In the last sentence, since there was no statistical difference, the authors cannot claim 'higher mortality in SOYBEAN' group.

Background:

Second sentence: mention which complications are reduced. (line 4).

Line 9: Mention which complications are attributed to lipid component.

The background section does not match the results in the abstract (with respect to the order of importance with which it is studied). Prealbumin, anabolism, catabolism markers are mentioned in the last sentence and there is no background explanation to explain the reason being its study here, even though prealbumin is a primary endpoint. Time for preparation is studied, but there is no information on it in the background section.

Treatment Protocol:
Line 19, page 8: Please mention the volume and concentration of dextrose
Page 9, line 7: Please mention the concentration of Intralipid.

Results:

Table 5:
Definitions of lung infections, scrotal infection and the details of non-specific infections should be provided.
Also were there data on positive blood cultures or any other microbial cultures?

Table 7:
What does investigations mean?
What does injury, poisoning and procedural complications mean?
What does procedural pain mean?

Hepatobiliary disorders are increased in OLIVE group. Does it reach significance?

Table 8
Page 59 and page 60: Mention units for both cholesterol and triglycerides

Table 9:
Please explain why the statistics are not provided for glucose results.
Also mention the units for glucose concentrations.

Figure 2:
Please mention CI intervals for p values, (even though they are pictorially depicted).

Figure 3:
Please provide information if the error bars are SD or SEM and also the statistic test used.

Results section:

Inflammation, oxidation and infections:
The authors should mention about bacteremia and positive blood cultures.
Lung infections should be defined.

Safety:
Page 20 line 5: The authors report statistically significant differences for the change from baseline. However my interpretation is that the analyses are ‘not for the changes from baseline’, however, the statistical significance is for “the differences between OLIVE and SOYBEAN group at day 5 and day 14”. In other words, the statistics is for inter-group difference and not within-group difference. If my interpretation is right, please correct the discrepancy in this passage and
the rest of the results sections.

Page 20 line 20.
I did not notice a significant change between the levels of bilirubin in table 8. I request the authors to correct this if required.

Discussion:

Line 3: Please mention that this is an ‘open labeled’ study’.

Line 14: Since it is not statistically different, it should not be stated that adverse events and mortality were higher in the SOYBEAN group.


Page 29 line 6: Once again, if it not statistically significant, the authors should refrain from saying that incidence of TEAEs was lower in OLIVE.

Page 30 line 21: Authors mention that mortality was higher in SOYBEAN, but it is not.

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

No disclosures to make