Reviewer’s report

Title: High potency fish oil supplement improves omega-3 fatty acid status in healthy adults: an open-label study.

Version: 1 Date: 10 June 2013

Reviewer: Nigel Terence Plummer

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Review: High potency fish oil supplement improves omega-3 fatty acid status in healthy adults: an open label study. Udani and Ritz

Overall Summary

The novel and most interesting aspect is the use of the web-based virtual CRO as a method of assessing the efficacy of an omega-3 supplement in a healthy population. As a reasonably robust and relatively low cost mechanism of assessing intervention in a healthy population (often more difficult than in the ‘already ill’) this methodology has considerable potential. I believe that this needs to be emphasised in all parts of the paper – from revision of the title through to conclusions.

By changing the emphasis, I think the focus shifts from potential weaknesses in the study in terms of hard outcome and clinical relevance to one of strength where the methodology provides an opportunity to demonstrate disease risk trends and health status in the normal population.

The other major revision that would considerably strengthen the study would be more interrogation of the results data – particularly with reference to the effects of the supplementation on the quartile baseline level variability in EPA/DHA membrane status of the study population – see below.

Detailed Comments

Abstract:
- line 28: to add ‘to compensate the low intake in general population’
- line 28: should say open label study
- line 36: should add the number of subjects and age
- line 40 and 43: to add comment on CRO – successful?

Introduction:
- Reference 4 is from 1993 – more recent reference for fish oil and blood pressure
- Line 54: to add the mechanisms how EPA and DHA as health promoting
- Line 65-67: sentence requires the reference
- Line 70: AHA recommendation for secondary prevention?
Materials and Methods:

General

section needs to be strengthened by:

- Details on exclusion/inclusion criteria
- Male/female distribution
- More detail on Omega-3 Index
- More detail on SF12 Health Survey e.g 1) when was testing done, 2) any evidence of adaptation to survey with repeated use.

- Line 99: should be ‘all dietary products were prohibited during wash out and intervention period’

- Following washout – were non-omega-3 supplements allowed for use – needs to be clarified - may have impact – e.g folic acid status supplementation profoundly effects DHA cell membrane concentration see Krauss-Etschmann et al 2007 Am J Clin Nut

Was the compliance to product recorded?

- Line 129: more details on mental and physical health assessment, reference range for the scores

Results:

General

The overall outcome of the study as a ‘one line’ primary end-point is positive. However, the data and interest of the study would be considerably enhanced if there was greater interrogation of the data. For example:

1) Correlation of the baseline measurement of Omega-3 index with the (Table 1) supplement intake analysis.

2) Division of impact of supplementation across initial quartiles of Omega-3 index concentration. E.g what is impact of supplementation on those subjects with baseline measurement at circa 3 as opposed to those at circa 11.

3)

- Line 142-143: What was the reason for the drop-out? Any adverse events?
  What was the ratio men: women

- Line 147: Results for HS-Omega-3 Index presented here and same in the Figure 1 (very simple presentation of graph, no axis label)

- Any differences between men and women?

- Line 150: should replace names of authors with the reference Numbers
Discussion and Conclusions

General:
The discussion and conclusions will change based upon the general comments and observations outlined above. Overall the conclusions made on this draft of the study are accurate and informative.

Specifics
- Line 175: perhaps the sentence to be better moved to Result section.
- Line 182: should be >8%
- Line 193: what the fish consumption recorded (oily fish)?
- Line 203: I am not sure about this sentence (the word ‘impractical’), it is contradictory to the sentence in the Line 185

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I work commercially in the area of nutritional supplementation, which includes the manufacture of omega-3 supplements. As such this article may have an impact upon the supplement industry with a potential fractional direct impact. Other than this, there is no other direct competing or conflicting interest.