Reviewer's report

**Title:** Effects of Protein-Enriched Meal in a Weight Loss Program on Liver, Kidney or Bone: a Randomized Controlled Trial

**Version:** 1  **Date:** 28 May 2010

**Reviewer:** Jennifer Keogh

**Reviewer's report:**

The following comments and changes are compulsory

Abstract

Subjects/methods

How many people completed the study?

Were they healthy subjects?

Please include data in the abstract for liver and renal function and bone density or remove these comments.

Introduction

Provide recent references for these statements or delete them as they do not add to the manuscript without references.

“A number of studies have suggested that protein is the most satiating macronutrient and promotes the retention of lean body mass.”

“There has been concern that the long-term use of high protein meal replacement may damage liver function, renal function, and bone metabolism.”

Reference 10 is now 9 yrs old please include a more recent reference

The introduction should focus more on the primary aim of the study which needs further clarification. Is the study’s focus on meal replacements or on comparing levels of protein intake? Please include an hypothesis.

Main paper

Please clarify why subjects who regularly drank more than one alcoholic beverage daily were excluded?

Were subjects matched for any characteristic before randomization into groups? Please include this information

Power analysis should be included

The primary outcome variable should be clarified

Analysis

The analysis should have been conducted with time as the within subject variable and group as the between subject variable. Further post hoc analysis is only warranted if there is a time by group interaction. An intention to treat analysis should be performed. Please clarify the statistical analysis.
Methods

How was the protein powder dispensed? Did subjects weigh the amount they were prescribed? Details should be provided.

Method for measurement of the biochemical variables is not included in the methods section. Please provide this information.

Was 24 hr urinary urea measured or urinary protein or urinary nitrogen? This is not clear from the methods & results.

Did the authors consider using the DEXA measurement of lean mass for estimation of protein requirements?

Is this measurement total body bone density? Were regional (spine, hip) sites measured?

Results

In subjects who withdrew from the study within the first week after randomization due to noncompliance how was noncompliance determined?

Baseline characteristics of study completers should be provided.

How much protein/day did the subjects consume?

How was compliance to the high protein diet determined?

Lipids

How was the analysis conducted? Was there an overall effect of time with a time by group interaction with post hoc tests showing the effects reported?

Renal

How was urine nitrogen measured? This is not described in the methods.

How was the analysis conducted? Was there an overall effect of time with a time by group interaction with post hoc tests showing the effect in the SP group reported?

Discussion

Given that the subjects in the study did not have abnormal liver function tests the discussion about non-alcoholic liver disease in not relevant in my view.

Total bone density is not a useful measurement of effects of diet on bone. Measurement of bone density at the hip and spine is more meaningful. The literature in relation to the effects of weight loss on bone density should be discussed.

Desirable changes

I suggest that the study by Noakes et al would be a useful addition to the paper as it shows that meal replacements are as effective as structured weight-loss diets.

Level of interest: Reject as not of sufficient priority to merit publishing in this journal

Quality of written English: Not suitable for publication unless extensively edited

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

Declaration of competing interests:
I declare that I have no competing interests