Reviewer's report

Title: Preliminary results, methodological considerations and recruitment difficulties of a randomised clinical trial comparing two treatment regimens for patients with headache and neck pain

Version: 1 Date: 15 June 2009

Reviewer: Michael Væth

Reviewer's report:

Statistical Review

Methods

1. In the section "Data reduction and analysis" the authors state that
"Differences between successive follow-up measurements within a treatment group were analysed using a one-way ANOVA."

A one-way analysis of variance is appropriate when comparing several independent groups. In the present situation the SAME patients are observed at several occasions, so this is clearly NOT a comparison of independent groups. The correct analysis is a repeated measurements ANOVA.

2. Three lines further down we learn that
"A posteriori, power calculations of the achieved results were performed".

Power calculations are useful/necessary when the study is planned. Once the data are collected, confidence intervals are the appropriate way to describe the information in the study. The full version of the revised CONSORT statement [1] gives the following advice (p. 670):

"There is little merit in calculating the statistical power once the results of the trial are known; the power is then appropriately indicated by confidence intervals".

Results

3. This is a randomized trial and the results section should focus on comparison of the primary (and secondary) endpoints between the two treatment groups. Time trends in one of the treatment groups are less interesting. Time trends should also be compared between groups.
4. Why was the study terminated before the necessary number of patients was included?

Table 2
5. Nineteen patients were randomised to UC and 18 to UCMT. Apparently, some patients drop out during follow up. This is not explained. Some patients may have more than one health care contact. The table would be more informative if also the number of patients with no contacts was shown.

Table 3
6. Give confidence intervals for the comparisons (difference of proportion, difference of means)

7. Here we have 18 patients in the UC group in follow-up week 12. The number was 17 in Table 2.

Table 4
6. Give confidence intervals for the comparisons (difference of proportion, difference of means)

8. Absenteeism follow-up week 26: "2/99"??

Table 5
9. The table gives no information about the alternative hypothesis for which the power is computed. As explained above, a posteriori power calculations are not useful, but they become completely useless when the value of the parameter under the alternative hypothesis is not specified.

Reference

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.