Reviewer's report

Title: Anesthetic injection versus ischemic compression on pain relief of abdominal wall trigger point from women with chronic pelvic pain

Version: 3  Date: 7 July 2015

Reviewer: Alisa Jane Stephens Shields

Reviewer's report:

Although the small sample size is initially disappointing, it is later explained that this was due to the study stopping early based on interim analysis. The trial is fairly well designed being a prospective, single-blind, randomized study, but the paper needs heavy language editing before it is ready for publication. There are frequent occurrences of poor word choice and awkward sentence structure that detract from the communication of important results for a medical condition that is not well understood, especially with regard to the efficacy of alternative therapies. Example – “Although little is known about the pathophysiology of them, a variability of methods has been preconized at clinical practices.” Further, there are many holes in the reporting of the analysis that need to be addressed prior to recommended for publication.

Major questions/issues –

1. What exactly does ‘open-blind’ mean? I believe the more familiar term is ‘single-blind’, which could describe the case in which patients, for example, are not blinded by study assessors are.

2. The sample size and statistical analysis sections are not clear at all. In the sample size section, which two-sided test was the sample size based on? Also, it’s clear that interim analyses were done because the trial was stopped early, but these are not discussed in the statistics section either. A weakness of the design is that it does not appear that the interim analysis was accounted for in the sample size calculation, which appears to describe a single test based on an alpha of 0.05. How many interim analyses were conducted during recruitment?

Regarding the statistical analysis section, it's not clear which variables were categorical and which were continuous. Also why are the researchers comparing times rather than outcomes at each time?

The researchers should strongly consider using a longitudinal approach such as marginal models by GEE or generalized linear mixed models rather than testing outcomes at each time point separately. This would be more appropriate for this type of data than testing at each time point separately, which wouldn’t account for multiple testing.

3. Was the analysis intent-to-treat? Or did it compare subjects based on some
level of compliance with their assigned treatment group?

4. The use of number needed to treat with regard to the magnitude of treatment is not well explained.

5. How were the p-values for the time effect calculated?

Minor Questions/Issues.

1. Criteria of ineligibility should be replaced with ‘Exclusion Criteria’

2. Does post-test describe the between groups test? This should be shown for the secondary analysis too, even if not significant.

3. Footnote on table 3 looks wrong and carried over from table 2.

4. While it’s too late to redo the randomization, it’s worthwhile to note for future studies that a variable block size makes for a stronger design than a fixed block size of 6.

**Level of interest:** An article of importance in its field

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

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

**Declaration of competing interests:**

I declare that I have no competing interests