Reviewer’s report

Title: Acupuncture for chronic prostatitis/chronic pelvic pain syndrome: study protocol for a randomized controlled trial

Version: 0 Date: 31 Aug 2017

Reviewer: David Atallah

Reviewer's report:

General observation

My general observation is that the study protocol is quite interesting but the paper requires a thorough editorial review by the authors for English grammar (e.g. tenses, the protocol has to be written is present and future tenses, not in the past tense, since the study did not start yet).

For example:

1. Page 4 - Line 60: replace "notified" with "will notify".

2. Page 8 - Line 58: replace "manipulate" with "handle".

3. Page 10 - Line 16: replace "discontinued" with "discontinue".

Methodology

The following points should be considered.

1. GCP: There is no statement whether the protocol complies with GCP. Please clarify how it complies or not.

2. Blinding: Probably the biggest problem with acupuncture studies is the lack of blinding. Despite the use of a sham procedure, it seems unlikely that patients would not guess which procedure is which, especially that patients will receive shallow needling. My guess is that most patients would know which treatment is which. This is particularly important for a subjective outcome measure like pain. Also, the blinding assessment can be biased, but in my opinion no better alternative is available.
3. Inconsistency in the definition of the primary outcome:

a. If you look at the abstract, the coprimary outcomes are the proportion of responders at 8 weeks and 32.

b. If you look at the main text, the coprimary outcomes are the proportion of responders at the end of 8-week treatment and 24-week after treatment weeks.

c. If you look at the study record detail on clinicaltrials.gov, you see that the original primary outcome measure is the 'proportion of responders at the end of 8-week treatment'.

4. Needles dispensation: provide details of how the needles will be dispensed and who provides the needles in this multi-center trial e.g. supplied locally or centrally. In case the needles to be used are the conventional needles, specify whether the needles in all centers are the same.

5. Acupuncturists: it is not well defined if the procedures are to be done by a single acupuncturist per site and if both treatment groups will be treated by the same therapist by site. If all interventions are to be delivered by a single therapist by site, that is both a strength and a weakness. It is a strength as it reduces variability, but a weakness as it limits generalizability. We have no way of knowing whether results would be completely different if delivered by a different therapist.

6. Rescue medicine: in case lots of analgesics will be used in this study, the results might be affected. All we can do is to wait for the results.

7. Insurance/indemnity: no information on insurance and indemnity are provided in the main text.

8. Study flowchart: it is recommended to include the study flowchart:

columns: Screen Visit, Week 1, Week 2

rows: Patient information and informed consent, Physical examination
**Level of interest**
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An article of importance in its field

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Please indicate the quality of language in the manuscript:

Not suitable for publication unless extensively edited

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Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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