Reviewer's report

Title: Use of botulinum toxin-a for musculoskeletal pain in patientes with whiplash associated disorders

Version: 1 Date: 17 November 2003

Reviewer: Michele Sterling

Reviewer's report:

General
This paper describes a research protocol for a proposed RCT on botulinum toxin therapy for chronic whiplash associated disorders. It is an interesting paper that has the potential to contribute to the treatment of whiplash. However, before the paper can be accepted there are several areas of the proposed protocol which need addressing and these are outlined below. The study design needs to be more clearly explained before it can be determined whether it will adequately test the proposed hypothesis. The writing needs review. There are frequent spelling and grammatical errors.

Discretionary Revisions (which the author can choose to ignore)

Minor Compulsory Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
1. Some of the inclusion/exclusion criteria are vague.
   ? The subjects that are being investigated appear to be WAD II subjects as per the Quebec Task Force Classification. This should be included.
   ? What is “myofascial pain originating in the neck”?
   ? How will subjects be excluded for “predominat operating fcators such as secondary gain, compensation, disability or psychosocial factors”. This needs to be clarified.
2. Study design
   ? It is not clear how the subjects will be randomised
   ? The treatment, placebo and control conditions are very unclear. The 3 conditions need to be fully explained.
   ? There is no mention of how the study will be double-blinded. How will the subjects be blinded to the intervention received? How will the examiners be blind to intervention allocation when the are taking the measures?
   ? How many subjects will be recruited? This has not been addressed with power analysis.
3. Outcome measures
   ? Measurement of cervical range of movement with a standard goniometer is unreliable. This could be improved with a more precise quantifiable instrument.
   ? Similarly measurement of palpation tenderness using response to manual pressure is fraught with problems. The use of pressure algometry would be preferable.
   ? The use of EMG is not well explained. What activities will the subject be performing whilst EMG is measured form upper trapezius. How will this be normalised? What EMG measures will be used?
4. Follow-up
   ? Why only a follow-up period of 8 weeks?
5. Statistical methods
What will be done with the dropouts?
Will and intention to treat analysis be used?

**What next?:** Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

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

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No

**Declaration of competing interests:**
none