Reviewer's report

Title: A longitudinal evaluation of the impact of a polylactic acid injection therapy on Health Related Quality of Life amongst HIV patients treated with anti-retroviral agents under real conditions of use.

Version: 1 Date: 18 September 2012

Reviewer: Richard Harding

Reviewer's report:

- Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

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

Background
1. You should spell out NI and PI
2. I think the word substantive should be changed? Do you mean substantial?
3. It is quite difficult to match the objectives in the abstract and main paper as they are written as 1-4 then main + 1-3.

- Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

This study addresses an important clinical issue and uses interesting methods to measure outcomes.

Background
4. Can you justify the claim that lipodystrophy is one of the main effects of treatment in the medium and long term with reference to the literature?
5. Can you briefly discuss what is known to date in effectiveness of fillers/other management of lipodystrophy? You discuss it at the end of the paper, but if you are presenting a new evaluative study you need to make a substantive argument of what this will add to the existing literature of effectiveness.
6. In terms of objectives can you clarify your safety objective in relation to any prior evidence from clinical trials? What new information is necessary?

Results
7. It is confusing talking about “the first secondary objective”.

Methods
8. You call this study a trial. In what sense is it a trial, and if it is what phase trial/design is it?
9. It is difficult to interpret the sentence: “The study did not alter patients’ usual medical management nor affect their physical or psychological integrity nor require specific monitoring visits. Indirectly nominal data concerning patients and nominal data concerning observer doctors were collected.” Is that that you were following patients under usual care, and that no additional visits were necessary, but that you did ask for additional information during usual care visits (which would have increased visit time?)

10. What do you mean by nominal data?

11. What are observer doctors, at this stage in the paper it is not yet described so cannot be understood by the reader.

12. What is a systematic patient diary?

13. How did you identify and approach doctors?

14. What was the study powered for if it was a trial, and what difference were you looking for?

15. Has the ABCD QoL tool been validated in France?

16. What do you mean it was a non-interventional study?

17. Can you explain what you mean by confirmatory analysis?

18. The analysis plan refers to qualitative variables but it is unclear what these are?

19. The analysis plan does not describe which time points you are referring to, how does time point fit into your analysis plan?

20. How did you handle missing data?

21. The analysis plan is generally very brief, what type of within-group analysis did you perform?

Discussion

22. What do you mean that the ABCD scores are actually comparable to?

23. How do you conclude that changes are “a little improved” or “somewhat improved”? Where do these labels originate?

24. You make a fair methodological point that, in light of no comparative group, it is true that this problem does not spontaneously improve. However, your main argument with respect to outcomes is that quality of life is important, and this may indeed regress to the mean. Please discuss. This is also relevant to the Abstract where you state that QoL changes are attributable to the treatment; the design means you cannot make that attribution.

25. Do you think any visible adverse treatment events might influence the visual scoring?

26. Why do you think there was so much missing data, even at baseline?

27. In the discussion you make the important statement that 5 prior studies have shown comparative effectiveness of this treatment, which begs the question of why this observational study adds something new, what is substantive?
Particularly in light of your safety objective, but do discuss all objectives.

28. It is difficult to support your final statement that doctors report satisfaction with the treatment when no data were collected on this.

29. In tables spell out SEM; again the analyses in the tables are not adequately described in the methods.

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

**Quality of written English:** Acceptable

**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'