Reviewer's report

Title: Patient-rated suitability of a novel electronic device for self-injection of subcutaneous interferon beta-1a in relapsing multiple sclerosis: an international, single-arm, multicentre, Phase IIIb study

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Reviewer: mark S Freedman

Reviewer's report:

The study is described as a phase IIIb, which usually examines efficacy, though the stated goal of this study is "feasibility" which makes it almost a pilot study looking to move towards a true efficacy study which might compare the new Rebismart with the previous injector in terms of adherence issues as well as perhaps drug delivery. This study does neither and as such should really not be tagged anything more than a phase IV observational study.

As the outcomes are just those of patients' subjective opinion of the device there is little objective evidence such as drug levels, biomarkers or even laboratory changes that would indicate that drug delivery is more efficacious, consistent and attains the desired therapeutic goals. A true phase IIIb study might also randomize patients to the old vs. new device and rate such important adherence factors such as ISRs, pain etc. or a much harder endpoint of simply those still using the device after a set amount of time.

It is odd that patients are asked to assess the new device after only a minimum of 6 weeks on the original one. Reality though was that most patients took the original for nearly a year.

Probably figures 2 and 4 are all that are required.

The observations are valid and probably warrant a true phase III study to demonstrate whether the device may well be superior than current delivery systems in terms of adherence or some other outcome, but the authors should state this.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I have no competing interests