Reviewer’s report

Title: Optimising recruitment of participants to a phase I/II trial using the internet and publicity releases through charities and patient organisations: analysis of the Adaptive study of IL-2 dose on regulatory T cells in type 1 diabetes (DILT1D)

Version: 2 Date: 26 October 2014

Reviewer: Sean F Dinneen

Reviewer’s report:

Summary:
The authors describe in great detail the methods used to recruit into a study (DILT1D) evaluating the mechanism of action of an experimental medicine (Aldesleukin) with the potential to be used as immunotherapy for patients with recently diagnosed type 1 diabetes. The Background, Methods and Results are clearly set out and read very well. The authors used 3 main sources to recruit potential study participants; diabetes clinics in the area around Cambridge; a register of patients with type 1 diabetes (who had expressed an interest in participating in research) and direct contact between potential participants and the study team via the internet and social media. A detailed breakdown of the number of contacts from each of these sources is provided. The register source provided the greatest number of potential subjects (but the lowest yield in terms of actual recruitment) while the internet source proved the most beneficial in terms of actual recruitment. The authors conclude that an active internet recruitment strategy (providing early contact between the potential participant and the study team) is superior to recruitment approaches that involve an intermediate person such as clinic personnel.

Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)
None

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
Page 5, Line 1: the word registrar is incorrect; should be register.

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)
It would be useful in the Discussion to place the (enormous) effort that went into recruitment for this mechanistic study in the context of other studies of treatments to prevent or treat type 1 diabetes using immunotherapy. The authors suggest that their analyses of patient participation are relevant to other mechanistic studies. What about their relevance to clinical trials of immunotherapy in type 1 diabetes?
Table 2 includes data on potential participants’ reasons for declining study involvement. It would be helpful to understand the reasons why the 45 individuals who did participate were motivated to do so. Were there any differences (e.g., employment status) between those who did participate and those who declined?

**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'