Reviewer’s report

Title: A multi-centre, randomised, double blind, placebo-controlled, parallel group trial of the effectiveness of the nocturnal use of a Temperature Controlled Laminar Airflow (TLA) Device (Airsonett) in adults with poorly-controlled, severe allergic asthma (The LASER Trial): Study protocol for a randomised controlled trial.

Version: 3 Date: 27 October 2015

Reviewer: José Antonio González Alastraúé

Reviewer’s report:

I’m not at all opposed to the publication of the protocol paper of the LASER trial. I have only minor remarks that could improve its readability a little. The most important topics, from my point of view, are correctly covered: there is only one primary outcome, although it could be defined more precisely (see the first of my minor objections); the sample size determination is clear and correct (I verified that the reported size corresponds to 80% power, with an analysis simpler than the planned one in the paper); the primary analysis, based on a Poisson regression model, is correct but could be more precise if you clarify the sentence ”... with log of time used as an offset variable”. Does this refer to the time until first asthma exacerbation? I wonder also if the secondary analysis should not include the center as another factor to adjust for.

Despite these non-important questions, which are easy to fix, the paper is well organized and written, readable and clear in general. The participants, interventions and outcomes are neatly described, and it's also worth pointing out the sections devoted to missing data, adverse events management, economic evaluation, ethics, role of the funder and sponsor or dissemination policy.

Minor points:

• I would ask the authors to clarify a bit the definition of the primary outcome measurement. They say that the patient will keep an "exacerbation diary", and they will be asked to contact the medical team "within 72 hours": It's not clear to me if the count of episodes will be mainly (or only) based on the patient notes or on contrasted reports received by the local trial team.

• "Methods" described in the Abstract say: 'A total of 222 patients [...] will be minimised ...' I would find the expression more accurate if it just says "allocated" or "assigned". I think that the authors mean that a minimisation algorithm is employed to allocate the patients to an intervention; this issue could be skipped in the Abstract section, in my opinion.

• I would recommend that the authors add the approval date (26 February 2014) by the NRES Committee instead of the reference. This is important to emphasize that the ethical approval was prior to beginning patient enrolment.
• Although they are likely well known, some abbreviations are missing from the List (e.g. GCP). The "Sino-Nasal Outcome Test" looks a bit strange: probably the term "22-item" should appear at the right instead of the left side.

• I haven't found any mention of plans for communicating important protocol amendments (SPIRIT, item 25).

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.