Reviewer’s report

Title: HATRIC: A feasibility study of Pelargonium sidoides root extract EPs®7630 (Kaloba®) for the treatment of acute cough due to lower respiratory tract infection in adults: study protocol for a double blind, placebo-controlled randomised trial

Version: 0 Date: 04 Feb 2019

Reviewer: Lawrence Mbuagbaw

Review's report:

HATRIC

The investigators report on the protocol of a feasibility study of pelargonium sidoides compared to placebo for the treatment of acute cough due to lower respiratory tract infections in adults.

I have the following feedback. Note that some of the comments cannot be used to modify the trial, given that it is ongoing in its current form, however, these concerns and limitations should be discussed/addressed in the published protocol.

The title should be rewritten to reflect the design better, i.e. double-blind, randomised placebo-controlled feasibility study instead of separating feasibility from the rest of the design.

In the background, reference is made to the Department of Health. Please rephrase this for international readers.

The study participants and enrolment section is worded as instructions, rather than a description of future plans. Rephrase: "consent to enter the trial must be sought...." to "we will seek consent..."

Other parts are written in the present tense. Please reword to future tense. It is as though excerpts of text were lifted from the investigators brochure.

Lack of data is insufficient justification to refuse participation or require contraception in women of childbearing age. Pregnant women get sick and sick women get pregnant. Reconsider explaining the risks and letting them decide.

The investigators mention sites in the UK, but it is unclear in what parts of the UK this research will be conducted.

Please replace "social demographic factors" with "sociodemographic" factors. Please add the word to your computer's dictionary.
Under "reasons for patient discontinuation", what does clinical decision entail and how it is different from recruiting physician's judgement? These should be operationalised with examples to prevent questionable exclusions of participants.

Under withdrawal, the wording is still odd: "Investigators should explain to patients…"

The sample size justification is well done, but it is unclear what the target recruitment rate is? How many people will be approached, how many will be eligible and what proportion of the eligible participants is 160?

Is recruitment here considered as number randomized?

The statistical analysis section is incomplete. At very least, you must conduct analyses to determine if you haven't your feasibility thresholds.

How many must you recruit to determine that larger trial is feasible?

How many must you retain to determine that a larger trial is feasible?

How is "delivery" measured?

Table 1 is helpful in understanding what you are looking for in terms of feasibility, but it does not tell us how you will interpret this information.

Set thresholds that will inform whether a larger trial is feasible.

Exclusion criteria number 6, ability to speak English is also a questionable one. Make efforts to accommodate "all" the people who show up for care.

**Level of interest**

Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

**Quality of written English**

Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

**Declaration of competing interests**

Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?
2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal

Were you mentored through this peer review?

No