Reviewer's report

Title: Efficacy of symptomatic treatment of the common cold in adults: randomized placebo-controlled clinical trial

Version: 2 Date: 25 February 2013

Reviewer: an A de sutter

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“1. Is the question posed by the authors well defined?
The question is well defined, but the relevance is not convincing. I agree with the authors that it would be important to find a formulation that decreases cold symptoms, but it would be more relevant to test this in comparison with existing safe symptomatic treatment, not with placebo.

2. Are the methods appropriate and well described?
This is a classic RCT, methodologically correct but with a small number of patients.
It is not clear why the authors used these inclusion criteria. The outcome measure is a symptom score while a general assessment of well being would have been much more relevant.

3. Are the data sound? Yes

4. Does the manuscript adhere to the relevant standards for reporting and data deposition? I think so. There are only graphs to present the results.

5. Are the discussion and conclusions well balanced and adequately supported by the data?
No,
- In the discussion it is stated that this is the first trial investigating an antihistamine, decongestive and analgesic combination. In 2012 a Cochrane review showed that in total there are 6 trials using a triple combination. In the paper the exact composition of the formula is not mentioned, so it is not possible to compare. The Cochrane review revealed that there is a small effect on general well being.
- The outcome measure used in this trial is a symptom score composed of 10 symptoms. Each symptom is score between 0 and 4, total of the score is 40. At the first evaluation (after 3 days) the difference is between the two groups is a little more than 1 point out of 40! It is statistically significant but it is very unlikely that this is clinically relevant! The only conclusion is that both groups after three days are almost completely free of symptoms.
- In general I think symptom scores are not the right outcome measure. Common cold and flu are self limiting diseases. The only outcome that is relevant is how
the patient feels. A general question about well-being would be much more relevant. It could be that someone still has a bit of a runny nose but that does not mean that it bothers him. On the other hand, if a person has e.g. a severe sore throat, he score 4/4 on this symptoms. All other symptoms could be minor so his total score could be low, but he would still be in a lot of pain.

- I do not understand the reasoning about the use of escape medication in the paper. What we really would like to know is whether the new formula is better than paracetamol. If we have an “escape product” like paracetamol (cheap and safe), why do we need a new formula?

- 6. Are limitations of the work clearly stated?

- There are no limitation mentioned, and the results are not compared with other similar trials.

- 7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?

- No, cfr supra. The authors missed the Cochrane review published last year on exactly the same kind of therapy as is being investigated here


8. Do the title and abstract accurately convey what has been found? No”

**Level of interest:** An article of insufficient interest to warrant publication in a scientific/medical journal

**Quality of written English:** Acceptable

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