Reviewer's report

Title: Clinical drug trials in general practice: a ten-year overview of protocols

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Reviewer: Noreen D Mdege

Reviewer's report:

This is a 10 year retrospective study of protocols of general practice (GP) clinical drug trials submitted to the Norwegian national medicine agency. The authors conclude that majority of clinical drug trials in GP settings were industry initiated. The manuscript is generally well written. However it requires major revisions to improve it and get it more focused. Here are my suggestions:

Background

Major compulsory revisions

1. After reading the background section I was still not clear what the aim and objectives of this study were; and I was not convinced about the novelty of this study? The authors state that the aim of the study was to gain systematic knowledge regarding clinical drug trials in Norwegian general practice. What does this exactly mean? They also state that they describe all clinical trials planned to be carried out in general practice. Why just describe the trials, and how does this add new knowledge- considering they reference 5 references who have already described similar trials before? They say none of these reports highlighted studies in general practice. However it is not enough to do something because it has not been done before because maybe the reason it has not been done is other people tried it and it was not worth doing. Not to say what you did here was not worth doing, but what I am trying to say is you have to build a stronger case of why this was worth doing.

2. The second sentence of the first paragraph implies that trials in hospital settings are not always generalisable to general practice. However there is no reason or explanation given as to why this might be so.

3. The second paragraph of the background section starts by referencing a study that judged GP trials initiated by pharmaceutical companies as having a low scientifically valid and clinically relevant results. This is an interesting point, but unfortunately the issue is not explored further. For example I would have wanted to know in what way? In-fact to me this could have formed the basis of a more interesting paper rather than description of the studies- i.e. exploring if, judging from the study designs proposed in the protocols and the subjects under investigation, the studies would contribute scientifically valid and clinically relevant results. This is also related to the fact that the authors highlight that industry has largely bypassed the voluntary quality and relevance checks by the subcommittee of the Norwegian College of General Practitioners.
Methods
The methods used for this study are appropriate.

Major compulsory revisions
1. The description of the methods could be improved by including details on the following:
   a. How many people were involved in the searching and selection of studies, and extracting data from the studies?
   b. Where there any procedures in place to minimize errors in the searching and selection of studies for inclusion; as well as in data extractions?
2. What was the rationale behind including studies that were a combination of general practice (GP) and specialist care settings? Was there any cut-off point used for inclusion of such trials? For example if only 5% of study participants were to come from general practice and the remaining 95% from specialist care settings, would the study still be eligible? Considering that these studies that were a combination of GP and non-GP settings form the bulk of the studies analysed here- how do the results then truly represent studies conducted in GP settings? Why did the authors not concentrate on the 45 that were solely in the GP setting and do a more details study of these?

Results
Minor essential revisions
1. There are a number of typos and omission of some words in the first paragraph of the results section
2. Table 1- Zeros missing for some of the years under Researcher initiated column.
3. Two table 3s and no table 2?

Discussion and conclusions
Discussion is well written with some very interesting points raised.

Major compulsory revision
1. I think the conclusions have to follow directly from the aims and objectives, and the results obtained from the study. This is not the case at present. The first sentence reads “it is a challenge for general practice to increase the number of clinical trials in general and non-commercial clinical drug trials in particular.” Although this sentence might be true, it is not rooted in the results of your study, nor is it related to the aims and objectives of this study (you did not set out to find how challenging it was to increase the number of clinical trials in GP settings)- so why is it the opening sentence of the conclusion? For the conclusion it would be better to limit it to your main findings and the policy and practice implications of your results.
**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 declare that I have no competing interests.