Reviewer’s report

Title: Adverse outcomes associated with opioid prescription for acute low back pain: A systematic review protocol

Version: 0 Date: 14 Mar 2017

Reviewer: Tesfa Habtewold

Reviewer's report:

I have reviewed this protocol with great interest. Given the absence of systematic review, this study will add relevant evidence for clinical practice. I really appreciate authors effort to develop this protocol. Nonetheless, there are major issues that need to be addressed before further steps.

Don't reply in the main document. Write your reply separately.

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Abstract

• Background_ line 52-53: Your major objective is about safety, not about effectiveness. Therefore this argument is not correct.

• Methods/design_ line 59: change clinical trials by Randomized control trails. In addition, Add information regarding how the quality of studies will be checked? How heterogeneity of studies will be checked? How publication bias will be checked? What model will you use to pool estimates?

• Discussion: Summarize what is known before in one sentence and add in this section.

• Systematic review registration: The title is different from the submitted manuscript “The risks of prescription opioid abuse following acute lower back pain: a systematic review and meta-analysis”. Check other inconsistencies as well.

Background

• Line 72-76: Write concisely. Incomplete sentences and disorganized phrases.
• Line 77: Acute pain or ALBP??

• Line 83 & 84: Which guidelines? I would prefer to name it.

• Line 88: write numbers in words whenever it is below 100.

• Line 91: Be specific. Effectiveness, addiction, adverse events are broad topic. Introduce these topic in a very organized way if you are really concerned.

• Line 99: Is it different form opioids prescription? If so please define it. Otherwise, use it consistently either opioids prescription or prescription opioids.

• Line 108: Non-medical ??? Not clear. Is it over the counter drug or any non-physician prescriptions???

• Line 110-115: irrelevant.

Objectives

• What is the difference between objective one and two? I believe obj 1 can be addressed by obj 2

• Obj 3: Is it a kind of identifying susceptible groups?

• Line 129-137: Is it different from the above three aims???? If not, avoid repetition, merge together and summarize it. In general, the objectives are unclear.

Methods and Materials.

• It is not well organized.

• Add “Protocol and registration” subheading between line 138 & 139 and relevant explanations. See example from other published protocols.

• Line 139: Data source and Search strategy

• Line 147-149: revise it.
• Line 150-155: Focus on systematic ways of searching articles. Otherwise you will miss important studies. These three explanation are not systematic ways.

• Line 155: A preliminary…..>> irrelevant.

• Table 1:

  o This is not sufficient and difficult to replicate by other researchers.

  o Consult Medical Information specialist.

  o Develop a standard search strategy for all databases using relevant boolean operators. Look examples from previously published protocols.

  o Check whether generic or brand drug name used. It must be only generic name used as search word.

  o Supplement it as additional file.

• Merge type of studies and participants section and use a subheading “Inclusion and Exclusion criteria”. Organize either of the following ways:

  o First inclusion then exclusion OR

  o First studies inclusion and exclusion then participants inclusion and exclusion.

• Line 172-179: Will you exclude studies if any of these not reported?

• Line 186-187: such…delete this sentence.

• Line 195-198: In addition…..move it to statistical analysis section.

• Line 204: Follow up duration six months…why?

• Line 208: delete this sentence “We will refer to the inclusion and exclusion criteria to assess study eligibility during screening.”
• Line 211: What Kappa value will you use as a cut-off point? If the agreement is low, what will you do?

• Line 212-216: Not clear.

• Line 214-216: This is a result reporting format. Nothing related with selection of studies.

• Line 218-226: Which one of them will be reported in the final result. Just focus only about these relevant information. Personally, for example the title of journal, is not relevant and other.

• Data extract and management: How will you manage all your references? Rework, Endnote? Medline? Others??

• Line 230: Newcastle-Ottawa Scale is recommended only for cohort and case-control studies. How will you check the quality of cross-sectional studies?

• Line 244: Change statistical analysis by Data synthesis and Statistical analysis.

• Line 254-257: check duplication of idea.

• Line 261-263: If…. move it to subgroup analysis section.

• Line 268: We will contact study authors in order to verify key study characteristics………… Is it feasible? You know authors are busy.

• Line 271-273: sensitivity…. move to sensitivity analysis section.

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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
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