Reviewer’s report

Title: Pharmacologic and Surgical Therapies for Patients with Meniere’s Disease: A Protocol for a Systematic Review and Meta-Analysis

Version: 0 Date: 08 Mar 2019

Reviewer: Reint Meursinge Reynders

Reviewer's report:

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Full title: A Protocol for a Systematic Review and Meta-Analysis of Pharmacologic and Surgical Therapies for Patients with Meniere's Disease

Article Type: Protocol

Associate Editor: Reint Meursinge Reynders

Peer reviewer: Reint Meursinge Reynders

Recommendation: Minor revision

Milan, March 8 2019

BRIEF SUMMARY OF THE PROTOCOL OF THE SYSTEMATIC REVIEW
In this protocol for a systematic review the authors report that they plan to conduct a systematic review and meta-analyses/network meta-analyses that will assess the relative effects of competing pharmacological and surgical interventions for management of Meniere's disease in adults.

STRENGTH OF THE PROTOCOL OF THE SYSTEMATIC REVIEW

The authors of this protocol plan to address important research questions.

The outcomes of the completed systematic review could benefit a large population (adults with Meniere's disease) both short-and long-term and could influence future health policies.

The authors also planned to assess adverse effects of the intervention.

SUMMARY OF KEY LIMITATIONS OF THE PROTOCOL OF THE SYSTEMATIC REVIEW

Several key items of the PRISMA-P checklist were missing or need to be restructured.

METHODS OF THIS PEER REVIEW

I used the PRISMA-P checklist and its pertinent guiding paper (Moher 2015a, Shamseer 2015) and the Methodological Expectations of Cochrane Intervention Reviews (MECIR) standards (Higgins 2016a, Higgins 2016b) to assess how this protocol was reported.

I further consulted the PRISMA checklist and its guiding document (Liberati 2009, Moher 2009), The RoB 2 tool (Higgins 2018), the ROBINS-I tool (Sterne 2016) and the AMSTAR 2 tool (Shea 2017).
I also consulted the strategies to consider when peer reviewing a systematic review as described by Moher (2015b).

For the abstract we will use the PRISMA for Abstracts Checklist (Beller 2013).

My comments and suggestions are presented under here and follow the order of the 17 items of the PRISMA-P checklist (Moher 2015a, Shamseer 2015).

REPORTING AND METHODOLOGICAL ISSUES

ABSTRACT

Comment:

The submission guidelines of the journal Systematic Reviews state that the Abstract of a protocol of a systematic review should not exceed 350 words.

The current abstract has a word count of 390 words.

I would suggest to cut parts of the background section of the abstract.

SECTION 1: ADMINISTRATIVE INFORMATION

TITLE (ITEM 1)
Item 1a: Identification.

Identify the report as a protocol of a systematic review

Comment:

Please place 'Protocol for a systematic review' at the end of the title.

Pharmacologic and Surgical Therapies for Patients with Meniere's Disease: A Protocol for a Systematic Review and Meta-Analysis

This order better catches the attention of the reader.

Item 1b: Update.

If the protocol is for an update of a previous systematic review, identify as such

Comment

I have no issues.

REGISTRATION (ITEM2)

If registered, provide the name of the registry (such as PROSPERO) and registration number
Comment:

The manuscript was registered in PROSPERO.

I ask the authors to update their registration in PROSPERO at the completion of all revisions of this protocol.

AUTHORS (ITEM 3)

Item 3a: Contact information.

Provide name, institutional affiliation, and email address of all protocol authors; provide physical mailing address of corresponding author.

Item 3b: Contributions.

Describe contributions of protocol authors and identify the guarantor of the Review.

Comment:

Under the subheading 'Authors' contributions' (Lines 376-378), please include (if this is the case) that all authors approved the final submitted version of the manuscript.

AMENDMENTS (ITEM 4)
If the report represents an amendment of a previously completed or published protocol, identify as such and indicate what changes were made; otherwise state plan for documenting important protocol amendments

Comment:

Not applicable

SUPPORT (ITEM 5)

Item 5a: Sources.

Indicate sources of financial or other support for the review

Item 5b: Sponsor.

Provide name of the review funder and/or sponsor

Item 5c: Role of sponsor and/or funder.

Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol

Comment:

I have no issues
SECTION 2: INTRODUCTION

RATIONALE (ITEM 6)

Describe the rationale for the review in the context of what is already known

Comment:

Please include which stakeholders (patients, clinicians, researchers etc.) were involved in the development of the research questions (Cowan and Oliver 2013).

How were these questions prioritized?

OBJECTIVES (ITEM 7)

Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)

Comment:

Please create a new heading 'Objectives' at the end of the Background section and formulate primary and secondary objectives using the PICOT acronym.

Please also include the assessment of adverse effects.

I understand that possibly not all PICO items are applicable.
SECTION 3: METHODS

ELIGIBILITY CRITERIA (ITEM 8)

Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review.

Comment:

Please adopt the order of the PRISMA-P statement and present the eligibility criteria prior to data sources and search for studies.

Comment:

In lines 199 and 200 the authors included a minimum follow-up of 6 months, but please put this under a separate subheading 'timing'.

Explain what follow-up means in the case of multiple interventions or combined interventions: e.g., 6 months after the first intervention or 6 months after the last.

Please also report eligibility criteria for the setting and language.

INFORMATION SOURCES (ITEM 9)
Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage

Comment:

Please adopt the order of the PRISMA-P statement and present the eligibility criteria prior to the information sources.

Comment:

Please adopt the terminology 'Information sources' and not 'data sources'

Comment:

Are authors of included studies contacted to verify eligibility?

Comment:

Please describe whether authors of included studies, topic specialists, and research sponsors will be contacted to obtain information on unknown and on-going studies.

SEARCH STRATEGY (ITEM 10)

Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated

Comment:
The authors combined the Information sources and the search strategy under one heading which is fine, but please change the term 'Search for studies' to 'Search strategy'.

The overall heading will be 'Information sources and search strategy'.

Comment:

Please state that when the search strategy has been completed its limitations will be given for example: language restrictions, time or financial constraints etc. (Shamseer 2015).

Comment:

I am not a topic expert nor an information specialist, but I need to know whether pertinent experts, medical encyclopaedias/dictionaries, and sources on the internet were consulted to identify pertinent MeSH terms and keywords.

STUDY RECORDS (ITEM 11)

Item 11a: Data management.

Describe the mechanism(s) that will be used to manage records and data throughout the review

Comment:

I have no issues
Item 11b: Selection process.

State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (screening, eligibility, and inclusion in meta-analysis)

Comment:

Please indicate which reviewers will do the study selection. Please abbreviate their names, e.g., 2 operators (NA and WC).

Readers want to know which authors will conduct these procedures, i.e., are they topic experts or methodologists or a combination of both?

Comment:

The excluded studies and the rationale for their exclusion will be given in an additional file to the completed review. Please state this in the protocol.

Comment:

The sentence (in lines 218 and 219):

'Studies included in existing reviews will be inspected to confirm that no relevant studies have been missed' should go to the section 'Information sources and search strategy'.
Item 11c: Data collection process.

Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators.

Comment:

Please consider Shamseer's statement (2015) in the PRISMA-P guideline:

'Data extraction forms should be developed a priori and included in the published or otherwise available review protocol as an appendix or as online supplementary materials.'

I ask the authors to apply this statement.

Define all data items in detail in these extraction forms (See ITEM 12) and upload these forms to an additional file.

Comment:

Please explain how to deal with duplicate, overlapping, or companion studies.

DATA ITEMS (ITEM 12)

List and define all variables for which data will be sought (such as PICO items, funding sources) and any pre-planned data assumptions and simplifications.
Comment:

Please pre-specify all data items that will be extracted in the data collection forms and define them precisely (See ITEM 11c).

Try to anticipate to as many uncertainties as possible that could arise and explain assumptions that might be made (Shamseer 2015).

OUTCOMES AND PRIORITISATION (ITEM 13)

List and define all outcomes for which data will be sought, including prioritisation of main and additional outcomes, with rationale

Comment:

The section 'Outcomes and prioritisation' is missing in this protocol.

Please note that the section 'Outcomes and prioritization' should occupy a substantial part of the protocol (Shamseer 2015).

Please consider that one of the key reasons to prepare a protocol is to carefully define outcomes a priori in order to reduce bias related to selective reporting of outcomes (Shamseer 2015).

Comment:

Parts of the information on outcomes are listed in the section 'Approaches to evidence Syntheses.'
I ask the authors to transfer this information to the section 'Outcomes and Prioritization' and to present prioritized core outcome sets (COMET 2019) for Meniere's disease.

I understand that not all outcomes can accurately be predicted a priori, but this should also be explained in this section.

RISK OF BIAS (ITEM 14)

Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis

Comment:

Please explain whether the Cochrane risk of bias tool for RCTs will also be used for quasi-randomized trials, since such trials are considered according to the eligibility criteria.

Comment:

Please note that reference 19 does not refer to the latest version of the Cochrane risk of bias tool for RCTs, which is now the RoB 2 tool.

In October 2018 this tool was revised (See reference under here: Higgins 2018).

DATA SYNTHESIS (ITEM 15)

Comment:
The structure and accessibility of this section will improve when subdividing it under 4 subheadings as outlined in the PRISMA-P Statement:

Items 15a-15d (Shamseer 2015).

META-BIAS (ES) (ITEM 16)

Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)

Comment:

Please expand on strategies for assessing publication bias and selective outcome reporting.

CONFIDENCE IN CUMULATIVE ESTIMATE (ITEM 17)

Describe how the strength of the body of evidence will be assessed (such as GRADE)

Comment:

Please report how the confidence in quantitative (Schünemann 2013, Schünemann 2016) and qualitative synthesized findings will be assessed.

For the qualitative findings please scrutinize the site of the Cochrane Qualitative & Implementation Methods Group (CQIMG 2018).
DISCUSSION:

Comment:

Please present the strengths and weaknesses of this study.

Comment:

In line 334, please provide the reference for COMET.

REFERENCES FOR THIS PEER REVIEW

Beller 2013


COMET 2019


Cowan and Oliver 2013

CQIMG 2018

Cochrane Qualitative and Implementation Methods Group (CQIMG) [online] Available from:

Higgins 2016a


Higgins 2016b


Higgins 2018

Liberati 2009


Moher 2009


Moher 2015a


Moher 2015b


Schünemann 2013

Schünemann 2016


Shamseer 2015


Shea 2017


Sterne 2016

Systematic Reviews 2019


**Level of interest**
Please indicate how interesting you found the manuscript:

An article of importance in its field that should be highlighted to relevant networks

**Quality of written English**
Please indicate the quality of language in the manuscript:

Acceptable

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

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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?

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5. Do you have any other financial competing interests?
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If you can answer no to all of the above, write 'I declare that I have no competing interests' below.
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Were you mentored through this peer review?

No