Reviewer’s report

Title: Real-Life Assessment of Aripiprazole Monthly (Abilify Maintena) in Schizophrenia: A Canadian Naturalistic Non-Interventional Prospective Cohort Study

Version: 0 Date: 26 Dec 2018

Reviewer: Lone Baandrup

Reviewer's report:

This is a prospective cohort study of subjects with schizophrenia treated with AOM after the discretion of their treating physician. The study is open-label and uncontrolled. The study investigates pragmatic functional outcome measures in an unselected clinical sample. The study aims to add data on effectiveness of AOM as a supplement to RCTs with narrow eligibility criteria and thus questionable external generalizability.

The study is funded by the pharmaceutical industry and thus needs to clearly document that design, analyses and interpretation is not biased. To ensure this, I recommend the following adjustments:

1) Background section: The trial was registered at clinicaltrials.gov. Not all secondary outcomes registered in the protocol are reported in the manuscript. The introduction states that only 'clinically relevant' outcomes are reported. To avoid presentation bias, all planned outcomes should be reported. One of the non-reported pre-planned outcomes is 'remission' which is indeed clinically very relevant in a pragmatic study like this and thus the authors' reason for not reporting all pre-planned outcomes does not seem justified. All planned outcome should be reported and commented on in order to be sure that not only outcomes with favorable results were reported. Of course, increasing the number of outcomes should be accompanied by considerations of the need to adjust for multiple comparisons.

2) Methods section: The original power analysis should be reported including the adjustments that were made due to the interim analysis. It should also be stated who was in the committee deciding to stop the study pre-term due to better than expected results.

3) Limitations section: The results reported in the manuscript show very high effect sizes compared with RCTs and the limitations of the current design should be briefly stated.

4) Data sharing: Why can't the anonymized data be made available for e.g. meta-analytic purposes?
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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

Acceptable

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