Reviewer’s report

Title: Efficacy of Botulinum Toxin A in Modifying Spasticity to Improve Walking and Quality of Life in Post-Stroke Lower Limb Spasticity - a Randomized Double-blind Placebo Controlled Study.

Version: 1 Date: 15 Apr 2019

Reviewer: Reviewer 2

Reviewer's report:

PEER REVIEWER ASSESSMENTS:

OBJECTIVE - Full research articles: is there a clear objective that addresses a testable research question(s) (brief or other article types: is there a clear objective)?
Yes - there is a clear objective

DESIGN - Is the current approach (including controls and analysis protocols) appropriate for the objective?
Yes - the approach is appropriate

EXECUTION - Are the experiments and analyses performed with technical rigor to allow confidence in the results?
N/A - no experiments or analyses

STATISTICS - Is the use of statistics in the manuscript appropriate?
N/A - there are no statistics in this study

INTERPRETATION - Is the current interpretation/discussion of the results reasonable and not overstated?
N/A - no results to interpret

OVERALL MANUSCRIPT POTENTIAL - Is the current version of this work technically sound? If not, can revisions be made to make the work technically sound?
Yes - current version is technically sound

PEER REVIEWER COMMENTS:

GENERAL COMMENTS: Post-stroke lower limb plasticity (PSLLS) is a common co-morbidity of stroke. PSLLS adversely affects the ability to walk and diminishes quality of life in patients. Botulinum toxin A (BT) improves focal spasticity. In this study protocol manuscript, the authors detail an upcoming 80 patient randomized, double-blind placebo controlled study to determine whether BT improves lower limb spasticity and improves functioning (mobility, walking, activities of daily living, quality of life) in stroke survivors.
The authors outlined the parameters of the upcoming trial, which is designed to assess the efficacy of BT, vs saline (placebo) injection, in conjunction with routine physiotherapy and standard care. The background and rationale are clearly articulated, including the potential issues with earlier, less robust trials. Proposed endpoints in this study are state of the art and inclusion/exclusion criteria, randomization procedures, and statistical analyses are defined. My only comment is there should be more detail regarding the stroke diagnosis of the patient - will CT scans be used as a means to determine ischemic vs. hemorrhagic stroke and will the authors assess the relationship between lesion sizes (infarcted lesion, size of initial hemorrhage) with outcome? This could be added to the inclusion/exclusion criteria for a more robust description of the patient population.

REQUESTED REVISIONS:
No revisions are necessary to ensure the soundness of the work. This is a study protocol. My only suggestion would be to include some comment about how ischemic vs. hemorrhagic patients will be diagnosed and will lesion size be used to match patients between placebo and BT groups? This would improve the clarity of the protocol.

ADDITIONAL REQUESTS/SUGGESTIONS:
No additional revisions, this is a well defined study protocol to detail and upcoming clinical trial of BT in post-stroke patients.

Note: This reviewer report can be downloaded - see attached pdf file.

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.

Unable to assess

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.

Not relevant to this manuscript
Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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