Reviewer’s report

Title: Interstitial pneumonia and other adverse events in riluzole-administered amyotrophic lateral sclerosis patients: a retrospective observational study

Version: 1 Date: 24 Dec 2018

Reviewer: Mamede de Carvalho

Reviewer's report:

In this study the authors approached side-effects of riluzole treatment in a small population of ALS patients. They mention increased liver enzymes and interstitial pneumonitis as relevant observations. In my personal experience of over 1500 patients treated with riluzole, the amount of drop-outs have been quite small (<5%) and the number of patients stopping the drug due to liver problems have been insignificant (<2%).

In this report, the value of threshold for defining abnormal liver enzymes increase is not set (the proposed limit is 3 x upper limit of normal for ALT and AST). Interstitial pneumonitis as a complication of riluzole treatment is not part of my medical experience, but chronic food microaspiration (common in ALS) is a classical cause of Idiopathic Pulmonary Fibrosis (Sweet MP, Patti MG, Hoopes C, Hays SR, Golden JA. Gastro-oesophageal reflux and aspiration in patients with advanced lung disease. Thorax. 2009;64:167-73). Other mentioned adverse events are very vague or related to disease progression.

There is no reason to stop riluzole treatment when FVC declines below 60% of the predicted value, this was an eligibility criteria in the original trial, but treatment was not interrupted when FVC decline below that value.

Clinical reports are very poorly written and Discussion is too long

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

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

Unable to assess

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:

Not suitable for publication unless extensively edited

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