Reviewer’s report

Title: Real World Experience of Patients with Amyotrophic Lateral Sclerosis (ALS) in the Treatment of Spasticity using Tetrahydrocannabinol:Cannabidiol (THC:CBD)

Version: 0 Date: 19 Jun 2019

Reviewer: Susanne Petri

Reviewer's report:

The authors present a retrospective monocentric cohort study to analyze the effect of off-label treatment with Delta-9-tetrahydrocannabinol (THC):cannabidiol (CBD) oromucosal spray (THC:CBD) on spasticity in 32 ALS patients.

They found that the drug was used in a wide dose range from daily high or low-dose to infrequent administration.

Patient satisfaction was assessed by the Net Promoter Score (NPS) and the Treatment Satisfaction Questionnaire for Medication (TSMQ-9) via telephone surveys or online assessment using a digital patient management platform. Higher recommendation rates were found in patients with more severe spasticity.

As few data and only one phase II controlled trial on the impact of THC:CBD exist for this indication, the presented results are worth reporting to increase awareness regarding this potential alternative to other drugs to treat spasticity in ALS. The study further emphasizes the general need of controlled trials to increase the level of evidence regarding symptomatic treatment of ALS.

While this study highlights the merits and benefits of the real word evidence approach in addition to clinical trials, a larger patient cohort, more detailed clinical characterization of patients as well as longitudinal data collection would have further strengthened the study.

Even though a comparison of different antispastic treatments was not the aim of this study, it should however be presented if/ how many of the patients also used other concomitant medications to alleviate spasticity, pain or muscle cramps.

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?  
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Unable to assess

Are the conclusions drawn adequately supported by the data shown?  
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