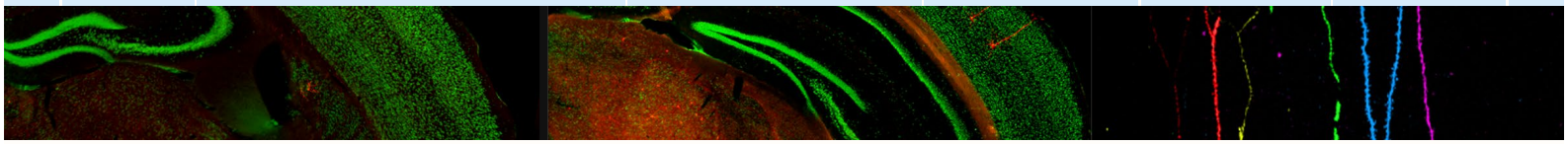

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AAN 2017: An Emerging Clinical Trial Endpoint Gathers Strength in ALS

May 8, 2017 News in Brief Michelle Pflumm

A new outcome measure may expedite testing of therapies for ALS according to a retrospective analysis presented at the 69th Annual Meeting of the American Academy of Neurology (AAN 2017) in Boston. The strategy, developed by a research team led by Biogen's **Toby Ferguson**, involves manual strength testing of key muscles in the arms and legs. Changes in this outcome measure could be detected over time in people with bulbar and spinal onset ALS, which correlated with key functional outcomes including ALS-FRS, survival and forced vital capacity. A total of 924 people with ALS participated in the study.

Strength in fewer numbers? *A strength-based endpoint may help detect a potential therapeutic benefit in people with ALS. The approach, developed by Biogen, leveraged muscle measurements obtained during the phase 3 clinical trial of dexpramipexole (see January 2013 news). [Douma et al., 2014 under CC BY 2.0 license.]*

The approach, which is based on hand-held dynamometry, involves the quantitative strength testing of 4 sets of muscles; one pair in the hand, elbow, thigh and lower leg. The endpoint is based on the time it takes the first set of these muscles to completely lose strength during the course of the disease.

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The strategy, according to a power analysis presented at AAN 2017, requires as few as 200 people with ALS to detect a therapeutic benefit in a two-treatment one-year study. This is 25% of the number of clinical trial participants needed using ALS-FRS as the primary endpoint.

Together, the results suggest that quantitative muscle strength has the potential to be used as a primary outcome measure in clinical trials for ALS. The strategy may enable potential therapies for ALS to be evaluated for shorter time periods in a smaller sample size.

The findings come at the heels of a previous study, led by Barrow Neurological Institute's **Jeremy Shefner** in Arizona, which found that quantitative strength testing of key muscle groups in the clinical trial setting could reliably and reproducibly measure progression of ALS (Shefner et al., 2016).

The outcome measure, compared to existing approaches, is more sensitive and less time-consuming since it involves the measurement of 50% fewer muscles. The strategy, according to Ferguson, is now being further validated. Stay tuned.

Reference

Shefner JM, Liu D, Leitner ML, Schoenfeld D, Johns DR, Ferguson T, Cudkowicz M. Quantitative strength testing in ALS clinical trials. Neurology. 2016 Aug 9;87(6):617-24. [PubMed].

Further Reading

Shefner JM. Strength Testing in Motor Neuron Diseases. Neurotherapeutics. 2017 Jan;14(1):154-160. [PubMed]

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