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Change in timed walk as primary outcome measure of treatment response in HAMLET-P: HAM/TSP MuLticentre Efficacy trial-Prednisolone

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Background

In the absence of an internationally recognised biomarker of treatment response in HAM/TSP, the HAM/TSP clinial trial study group chose improvement of 10 meter time walk (TW) as the primary outcome measure for the HAMLET-P trial.

Aim

To define the minimum change in TW required for an observed treatment effect to be detectable and important. To calculate the sample size required for 90% power to detect this difference.

Methods

Prospectively collected TW (seconds/10m) of HAM/TSP patients from the four countries were submitted to two biostatisticians (Japan+UK). Analysis of covariance and log transformed TW were used.

Results

Matched TW data (baseline+6 months) were available for a total of 76 patients. Mean (SD,median) TW were 23.46 (±18.9,16.32) at baseline, 24.85 (±23.89,16.38) at 6 months. Mean (SD,median) log10m TW were 2.89 (±0.72,2.79) at baseline, 2.91 (±0.74,2.80) at 6 months. The estimated SD of log10m TW after adjustment for the baseline measurement was 0.26. With 30 participants/group, we have 90% power to detect a difference of ±0.21. This corresponds to a ratio of 0.81 or 1.23, so we could detect a decrease in time of 19% or an increase of 23%. With power 80% we could detect a difference of -15% or +18%.

Conclusions

Prospectively collected longitudinal data on TW is useful in measuring inter- and intra- patient variability of this clinical efficacy marker. To power HAMLET-P at 90%, a minimum of 30 patients are needed in each arm, to be increased by 3-5 patients/arm to cover for 10-15% estimated trial drop-out rate.

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