

## **Intercorrelations between the International Restless Legs Syndrome Rating Scale [IRLS] and other severity and quality of life scales**

**Kohnen R, Allen R, Oertel W, Walters A, Benes H, Schollmayer E, Grieger F, Moran K.**

**Background:** The SP790 study (ClinicalTrials.gov: NCT00136045) showed benefits of rotigotine over placebo in improving symptom severity (International Restless Legs Syndrome Rating Scale [IRLS]; Clinical Global Impression Severity Scale [CGI-1]; RLS-6) and quality of life (RLS-QoL) in patients with moderate-to-severe idiopathic restless legs syndrome (RLS). In order to provide clinical context for the IRLS, this *post hoc* analysis of SP790 data evaluated associations between the IRLS and CGI-1, the IRLS and RLS-6, and the IRLS and RLS-QoL.

**Methods:** Scale associations were analysed as categorical and continuous variables at baseline and end of maintenance (EoM) using data from the safety set (rotigotine- and placebo-groups combined). Changes from baseline to EoM in IRLS score versus comparator scale scores were also analysed.

**Results:** Categorical analyses showed a trend towards increasing IRLS severity category with increasing CGI-1/RLS-6/RLS-QoL score/category. For the continuous analyses, Pearson correlation coefficients showed correlations between the IRLS and comparator scales at baseline and EoM, as well as correlations for change from baseline to EoM.

**Conclusion:** Correlations between the IRLS and comparator scales were substantial. These data suggest the IRLS is a clinically meaningful scale, and support its use as a measure of RLS severity both in clinical trials and routine clinical practice.

Manuscript accepted for publication in Sleep Medicine (Allen et al.).