Background: Patients receiving injectable therapies for multiple sclerosis (MS) may experience barriers to treatment adherence related to factors such as injection site reactions (ISRs), injection site pain, and negative perceptions of the tolerability or ease of use of the drug-administration device. Self-injection devices have demonstrated the potential to reduce the incidence of ISRs and improve treatment adherence. The RebiSmart autoinjector is an electronic self-injection device designed to enhance patient satisfaction by offering improved ease of use and convenience, needle shielding, and adjustable injection parameters (e.g., needle depth, rate of injection). The device also monitors treatment adherence by recording injection times. Objectives: To present the design of a study to evaluate ease of use, patient acceptability and satisfaction, and functional reliability of the RebiSmart electronic autoinjector in patients using subcutaneous (SC) IFN-β-1a for the treatment of relapsing MS. Methods: The study is a 12-week, open-label, single-arm, multicenter phase 3b trial enrolling patients aged 18 to 65 years with relapsing MS (McDonald criteria) who have been undergoing treatment with IFN-β-1a 44 μg SC 3 times weekly (TIW) for ≥12 weeks. During the study, patients continue with IFN-β-1a 44 μg SC TIW injections using the RebiSmart electronic autoinjector. The primary end point of this study is the proportion of patients who rate the autoinjector as “easy to use” or “very easy to use” on a user trial questionnaire at the 12-week end point. Multiple secondary endpoints related to functional reliability, device characteristics, patient satisfaction, ease of use, and convenience are included based on answers to the questionnaire administered at weeks 6 and 12. A quality of life questionnaire is included at baseline and week 12. Monitoring of adverse events associated with treatment administration will be conducted throughout the study. Results: Enrollment for this trial will begin in February 2010 and will continue for 24 weeks or until 100 patients are enrolled. Conclusions: The data from this trial are expected to provide insights regarding the use of an electronic autoinjector for delivery of IFN-β-1a 44 μg SC TIW in patients with relapsing MS.

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