A SINGLE-USE AUTOINJECTOR FOR SELF-INJECTED SUBCUTANEOUS INTERFERON BETA-1A
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Background: Treatment adherence in patients receiving injectable therapies for multiple sclerosis (MS) can be negatively affected by the occurrence of injection site reactions (ISRs) and the patient’s subjective perception of tolerability and ease of use of the injection device. Studies have demonstrated that self-injection devices may reduce the incidence of ISRs. A ready-to-use, single-use autoinjector has been designed with the aim of simplifying subcutaneous (SC) injections of interferon beta-1a (IFNβ-1a) and improving patient satisfaction by eliminating the need for device preparation and featuring needle shielding both pre- and post-injection. Objectives: To present the design of a study to evaluate an investigational, ready-to-use, single-use autoinjector for self-injection of IFNβ-1a SC with respect to the following domains: ease of use, patient satisfaction and acceptability, and functional reliability. Methods: Patients aged 18 to 65 years with relapsing MS (McDonald criteria) who have been undergoing treatment with IFNβ-1a SC 44 μg 3 times weekly (TIW) for at least 12 weeks were eligible for this prospective, multicenter, open-label, single-arm, 12-week, phase 3b study. During the study, patients continue therapy with IFNβ-1a SC 44 μg TIW using the single-use autoinjector. The proportion of patients rating the autoinjector as “easy to use” or “very easy to use” on a user trial questionnaire at Week 12 is the primary end point. Functional reliability, ease of use and simplicity of the device, patient satisfaction, impact on patient perception of quality of life, and convenience based on responses to the questionnaire at week 12 are secondary end points. Assessments will also include safety, tolerability, and compliance with the autoinjector. Results: This study has completed recruitment of 109 patients with relapsing MS. Baseline demographics, clinical characteristics, and 6-week interim data will be presented. Conclusions: Data from this study will provide information regarding the ease of use, reliability, and patient acceptability and satisfaction with drug administration via a single-use autoinjector for self-injection of IFNβ-1a SC to treat relapsing MS.

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