Although the use of RCI in MS has increased over the last decade, there is limited information on the effects of RCI on outcomes in MS patients. This study was conducted to evaluate the safety and efficacy of RCI in MS patients who previously failed to respond to standard therapies.

Patients and study design

This was a multicenter, prospective, observational registry that aimed to enroll patients with MS who were being treated with RCI for MS exacerbations. A patient enrollment and data collection overview is presented in Figure 1. Only MS patients deemed appropriate for RCI treatment were entered into the study. Key inclusion and exclusion criteria are enumerated in Table 1. All treatment decisions were made at the discretion of the patient’s healthcare provider and were not influenced by the investigator or the sponsor. The study drug was not provided free of charge by the Sponsor. RCI was obtained through usual commercial channels for prescription medications.

Efficacy and safety assessments

The primary endpoint was change (from baseline to Month 2) in the MS Impact Scale (MSIS-29v1) physical subscale score. Secondary endpoints included change from baseline to Month 2 in the Expanded Disability Status Scale (EDSS), Global Impression of Improvement (CGI-I) scale, and number of exacerbations. Safety data (AEs and serious AEs [SAEs]) were collected at each usual care visit and at any time the investigator considered it appropriate.

Results

Patient disposition and demographics

A total of 122 patients were assessed for eligibility and 115 patients were enrolled. Among the 115 patients, 113 patients were treated with RCI, and 2 patients did not receive any doses of RCI. The average time since diagnosis of MS was 10.2 years. The number of exacerbations during the follow-up interval were defined as relapses. The results presented here pertain only to the 113 patients who received at least 1 dose of RCI.

Efficacy

After treatment with RCI, mean MSIS-29v1 physical subscale scores decreased from baseline by -5.17 at 2 months (P = 0.0002) and by 9.64 at 6 months postbaseline (P < 0.0001; Figure 2). A post-hoc analysis of EDSS data by the number of doses administered was also performed. EDSS scores showed improvement across all dose levels with greater improvement in EDSS scores compared to patients taking ≤5 doses of RCI (P < 0.0001; Figure 3). The average time since diagnosis of MS was 10.2 years.

Safety

A total of 83 AEs were reported by 35 (28.0%) patients. A total of 16 SAEs were reported by 11 (9.6%) patients. The number of AEs and SAEs for the number of doses administered are presented in Figure 4.

Conclusions

This was a multicenter, prospective observational registry that aimed to enroll patients with MS who were being treated with RCI for MS exacerbations. A patient enrollment and data collection overview is presented in Figure 1. Only MS patients deemed appropriate for RCI treatment were entered into the study. Key inclusion and exclusion criteria are enumerated in Table 1. All treatment decisions were made at the discretion of the patient’s healthcare provider and were not influenced by the investigator or the sponsor. The study drug was not provided free of charge by the Sponsor. RCI was obtained through usual commercial channels for prescription medications.

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