Title:

MoOzaRt: Impact of ocrelizumab on patient-reported fatigue in RMS patients

Short title:

Fatigue in ocrelizumab treated RMS patients

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Abstract:

Objective: Fatigue represents a major disease burden for MS patients. In the ORATORIO trial, the monoclonal anti-CD20-antibody ocrelizumab reduced fatigue in patients with primary progressive MS. MoOzaRt aims to assess the impact of ocrelizumab on patient-reported long-term (trait) and transient (state) fatigue and on factors possibly influencing fatigue in patients with relapsing forms of MS (RMS) receiving standard clinical care.

Methods: The ongoing non-interventional study MoOzaRt (ISRCTN55332718) plans to collect real-world data of 740 RMS patients initiating ocrelizumab. The primary endpoint is change in Fatigue Scale for Motor and Cognitive Functions (FSMC) total score from baseline to month 24 for evaluation of trait fatigue. Secondary endpoints include change in state fatigue from time narrow points prior to, during and after ocrelizumab infusions rated on a Visual Analogue Scale. Patients complete web-based questionnaires (e.g. MSIS-29, WPAI:MS) and scales during visits at months 0, 6, 12, 18 and 24. Change in EDSS and safety will also be assessed.

Results: From first patient in (Dec 28, 2021) to data cut-off (Aug 02, 2022), baseline data were available from 67 patients (85% female, mean age 38.2 years) recruited by 8 sites in Germany and Switzerland. Mean (±standard deviation (SD)) EDSS was 2.49±1.41. Mean number of relapses within the last 12 months prior to enrolment was 0.7. Mean (±SD) FSMC total score, cognitive subscore and

motor subscore was 53.3±23.4, 26.5±12.1, and 26.8±11.8, respectively, indicating that fatigue is highly prevalent and often severe.

Conclusions: We provide baseline data of the first 67 RMS patients entering the MoOzaRt non-interventional trial and expect to enrol the first 100 patients by Q4 2022. MoOzaRt will provide important data on the impact of ocrelizumab therapy on trait and state fatigue in RMS patients and give insights into potential correlations with other PROs.

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Disclosures

HS: Almirall, Biogen, Genzyme, Merck, Novartis, Roche, Teva // speakers bureau or advisory board, consulting fees, travel reimbursement; Biogen, Novartis, Teva // research grants; Biogen, Novartis, Roche // data monitoring or steering committees

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