

Serum neurofilament light levels in patients with PPMS following Ocrelizumab treatment

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Background: Neurofilament light (NfL) is released upon neuroaxonal injury in multiple sclerosis (MS) and correlate with T1 Gd+, T2 brain MRI lesions and disability as assessed by the EDSS. Ocrelizumab is an anti-CD20 monoclonal antibody therapy, and in a randomized double-blind placebo controlled study (ORATORIO) it has been shown to reduce disability progression among patients with primary progressive MS (PPMS).

Aim: To assess changes in serum NfL levels following Ocrelizumab treatment in patients with PPMS

Methods: we collected baseline and follow-up clinical and paraclinical data (EDSS, brain/spinal MRI data, MSQoL-54, performed laboratory tests, 25-foot walking test). Serum were collected by standards methods at baseline, at month 6, at 1 year and at 2 years. Untreated PPMS and sex and age-matched healthy donors have been used as controls. Longitudinal mixed effect models were used with random intercept for patients, drug x time interaction term, and adjusted for age and sex to assess the effects of Ocrelizumab on serum NfL levels.

Results:

54 patients treated with Ocrelizumab (median age 46, range 23-66 years) have been followed up for 1 year, and 22 for 2 years. At baseline, the median EDSS was 4.5 (range 3-8) and at 1 year the disability remained stable. Also T2 lesion number at MRI, the 25-foot-walking test an MSQoL-54 remained stable in the follow-up.

Baseline serum NfL were similar between patients with PPMS undergoing Ocrelizumab therapy and control PPMS patients (25.6 pg/ml SD 8.9 vs 27.2 pg/ml SD 9.2pg/ml), and higher in both cases in comparison to healthy controls (9.2 pg/ml SD 4.3 pg/ml, $p < 0.01$). Longitudinal changes in serum NfL are under evaluation.

Conclusion:

In real life setting, ocrelizumab was well tolerated without any serious adverse event. At 1 year there is no evidence of clear disease progression, but a larger number of patients and a longer follow-up is needed to confirm these data.