

ALEMTUZUMAB IMPROVES EXPANDED DISABILITY STATUS SCALE SCORES VIA EFFECTS ON FUNCTIONAL SYSTEMS – CARE-MS II

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Alemtuzumab is approved in 30 countries for relapsing-remitting multiple sclerosis (RRMS). In CARE-MS II (NCT00548405), RRMS patients who relapsed on prior therapy had significantly improved mean Expanded Disability Status Scale (EDSS) scores with alemtuzumab vs baseline and vs subcutaneous interferon beta-1a (SC IFNB-1a). This analysis assesses changes in EDSS functional system (FS) scores, important measures in earlier MS stages, when disability is evident in areas other than ambulation. Patients with EDSS score 0.0–5.0 were randomized to alemtuzumab (12 mg/day intravenously on 5 consecutive days at baseline and 3 consecutive days 12 months later) or IFNB-1a (44 µg SC 3 times/week). Logistic regression analyses compared the proportion of patients that improved vs remained stable/worsened at Months 6, 12 and 24 for each FS. Alemtuzumab patients had larger mean reductions from baseline in FS scores than SC IFNB-1a patients, with significant between-group differences in cerebellar, cerebral, pyramidal, sensory, and visual scores at Month 24. A greater proportion of alemtuzumab patients had improvements from baseline vs. SC IFNB-1a patients in all 7 FS; differences were significant for brainstem (Month 6: p=0.0386), cerebellar (Month 6: p=0.0007; Month 12: p0.0001; Month 24: p0.0001), cerebral (Month 6: p=0.0326; Month 24: p=0.0004), pyramidal (Month 24: p=0.0085), and sensory (Month 6: p=0.0123; Month 12: p=0.0107; Month 24: p=0.0021) scores. Improvement in all 7 FS contributed to reduction in mean EDSS scores after alemtuzumab. This suggests that alemtuzumab treatment increases the odds that preexisting impairment from prior MS attacks will improve, leading to meaningful recovery of neurologic function.

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