Background: Currently patients with relapsing-remitting multiple sclerosis (RRMS) are treated with chronic administration of disease-modifying therapies. Alemtuzumab administered for two brief annual cycles has demonstrated efficacy superior to that of subcutaneous interferon beta-1a (IFNβ-1a) in a 3-year trial with RRMS patients (CAMMS223), significantly reducing the relapse rate, risk for sustained accumulation of disability (SAD), and mean disability compared with baseline (all comparisons P < .001). Two years after their last alemtuzumab cycle, patients maintained a significant 70% reduction in risk for SAD and a significant 74% reduction in relapses compared with patients treated continuously with IFNβ-1a, as well as a mean point reduction of 0.38 from baseline on the Expanded Disability Status Scale score. Two larger studies are now evaluating the safety and efficacy of alemtuzumab compared with subcutaneous IFNβ-1a for treatment-naive RRMS patients (CARE-MS I) and RRMS patients who relapse on prior therapy (CARE-MS II). As alemtuzumab has demonstrated durable effects for many patients, we will investigate a novel MS treatment paradigm involving as-needed redosing. Objectives: To present the rationale and design of the novel as-needed treatment component of the CARE-MS Extension Study (CAMMS03409).

Methods: All patients from CAMMS223 and those completing CARE-MS I or CARE-MS II are eligible to enroll in the 3-year follow-up protocol examining the long-term safety and efficacy of alemtuzumab. Patients treated with alemtuzumab in their prior trial are eligible for as-needed alemtuzumab treatment upon evidence of resumed disease activity, as are former IFNβ-1a patients after they have completed two annual cycles of alemtuzumab. Qualifications for retreatment include relapse or a minimum of 2 new lesions on cranial/spinal magnetic resonance imaging (MRI) consisting of any combination of gadolinium-enhancing lesions or new or enlarging T2 lesions. Results: Criteria for retreatment were defined, and a novel treat-as-needed strategy will be explored in the CARE-MS Extension study. Assessments will include disability, relapse, MRI, quality of life, and safety. Conclusions: Evidence of the durability of infrequent alemtuzumab treatment is the impetus for investigating an as-needed treatment strategy in the Extension Study.

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