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Titel des Beitrags: Oral fingolimod or intramuscular interferon for relapsing multiple sclerosis.

Abstract:
Fingolimod (FTY720), a sphingosine-1-phosphate-receptor modulator that prevents lymphocyte egress from lymph nodes, showed clinical efficacy and improvement on imaging in a phase 2 study involving patients with multiple sclerosis. In this 12-month, double-blind, double-dummy study, we randomly assigned 1292 patients with relapsing-remitting multiple sclerosis who had a recent history of at least one relapse to receive either oral fingolimod at a daily dose of either 1.25 or 0.5 mg or intramuscular interferon beta-1a (an established therapy for multiple sclerosis) at a weekly dose of 30 microg. The primary end point was the annualized relapse rate. Key secondary end points were the number of new or enlarged lesions on T(2)-weighted magnetic resonance imaging (MRI) scans at 12 months and progression of disability that was sustained for at least 3 months. A total of 1153 patients (89%) completed the study. The annualized relapse rate was significantly lower in both groups receiving fingolimod—0.20 (95% confidence interval [CI], 0.16 to 0.26) in the 1.25-mg group and 0.16 (95% CI, 0.12 to 0.21) in the 0.5-mg group—than in the interferon group (0.33; 95% CI, 0.26 to 0.42; P<0.001 for both comparisons). MRI findings supported the primary results. No significant differences were seen among the study groups with respect to progression of disability. Two fatal infections occurred in the group that received the 1.25-mg dose of fingolimod: disseminated primary varicella zoster and herpes simplex encephalitis. Other adverse events among patients receiving fingolimod were nonfatal herpesvirus infections, bradycardia and atrophicventricular block, hypertension, macular edema, skin cancer, and elevated liver-enzyme levels. This trial showed the superior efficacy of oral fingolimod with respect to relapse rates and MRI outcomes in patients with multiple sclerosis, as compared with intramuscular interferon beta-1a. Longer studies are needed to assess the safety and efficacy of treatment beyond 1 year. (ClinicalTrials.gov number, NCT00340834.)

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