Study examines fingolimod therapy in patients with multiple sclerosis

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The medication fingolimod reduced inflammatory lesion activity and reduced brain volume loss in patients with multiple sclerosis who participated in a two-year placebo-controlled clinical trial and were assessed by magnetic resonance imaging (MRI) measures, according to a report published Online First by *Archives of Neurology*.

Fingolimod is the first in a new class of drugs called the sphingosine 1-phosphate receptor (S1PR) modulators that was recently approved at 0.5 mg once daily for the treatment of relapsing multiple sclerosis (MS), a debilitating disease of the central nervous system, according to the study background.

The inflammatory pathology of MS can be seen by counting gadolinium (Gd)-enhancing lesions on T1-weighted images or new and enlarging T2 lesions on serial MRI scans. The extent of hyperintense areas on T2-weighted images provides an indication of the overall burden of disease, the study background explains.

The study by Ernst-Wilhelm Radue, M.D., of the Medical Image Analysis Center, University Hospital, Basel, Switzerland, and colleagues included 1,272 patients who were part of the fingolimod FTY720 Research Evaluating Effects of Daily Oral Therapy in Multiple Sclerosis (FREEDOMS) clinical trial, a worldwide, multicenter effort. Patients received once-daily fingolimod capsules of 0.5 mg or 1.25 mg, or placebo.

"The anti-inflammatory effects of fingolimod therapy, as depicted by Gd-enhancing lesions and new/newly enlarged T2 lesions, were evident as early as 6 months after treatment initiation and were sustained over two years. Approximately half the patients receiving fingolimod therapy were free from any new inflammatory lesions throughout this 2-year study, compared with only 21 percent of patients receiving placebo," the authors comment.

Fingolimod, 0.5 mg (licensed dose), "significantly reduced" brain volume loss during the trial versus placebo, according to the study results. Brain atrophy is recognized as a useful way to monitor MS disease progression.

"These results, coupled with the significant reductions in relapse rates and disability progression reported previously, support the positive impact on long-term disease evolution," the study concludes.

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