

ONO-4641 pill reduced number of MS lesions in Phase II trial

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An investigational oral drug called ONO-4641 reduced the number of lesions in people with multiple sclerosis (MS), according to the results of a phase two clinical trial to be presented as Emerging Science (formerly known as Late-Breaking Science) at the American Academy of Neurology's 64th Annual Meeting in New Orleans April 21 to April 28, 2012.

For the study, 407 people between the ages of 18 and 55 with relapsing-remitting MS were randomly given placebo, 0.05 mg, 0.10 mg, or 0.15 mg of ONO-4641 once per day for 26 weeks. People were included in the study if they had two or more relapses in the two years prior to the study, one or more [relapses](#) within the year prior to the study or one or more new MS-related brain lesions, also known as Gd-enhancing lesions, detected on MRI within three months prior to the study. [Brain scans](#) were performed every four weeks from 10 to 26 weeks.

At the end of the study, people taking 0.05, 0.10, or 0.15 mg of ONO-4641 had 82 percent, 92 percent and 77 percent fewer Gd-enhancing [brain lesions](#), respectively, compared to placebo.

Adverse events appeared to be dose related and included [cardiovascular events](#), such as a slower heartbeat, blood pressure changes, and an AV block, which is the impairment of the conduction between the atria and ventricles of the heart. Other adverse events included liver enzyme elevations. In addition, grade four lymphopenia, which is an abnormally low level of lymphocytes in the blood, occurred in four percent of

people receiving the 0.15 mg dose of ONO-4641 and in one percent of those receiving the 0.10 mg dose.

"In light of recent issues in the oral MS drug market, this is welcome news," said study author Timothy Vollmer, MD, of the University of Colorado in Denver and a Fellow with the American Academy of Neurology.

Provided by American Academy of Neurology

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