Extending natalizumab up to 8 weeks shown safe and effective in patients with MS

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In a study of 1,964 patients with multiple sclerosis (MS) led by researchers at the NYU Langone Multiple Sclerosis Comprehensive Care Center, extending the dose of natalizumab from 4 weeks up to 8 weeks was shown to be well-tolerated and effective in patients, and resulted in no cases of the potentially fatal side effect progressive multifocal leukoencephalopathy (PML).

The drug showed similar efficacy in treating disease activity among patients, according to the study led by Lana Zhovtis-Ryerson, MD, an assistant professor of neurology at the NYU Langone Multiple Sclerosis Comprehensive Care Center.

The findings were presented at the American Academy of Neurology Annual Meeting held April 18-25, in Washington, D.C.

Natalizumab is an infusion drug known as a monoclonal antibody that is used to prevent MS symptoms and flare-ups and slow worsening disability.

However, taking the medication longer than two years may increase risk for a rare but potentially fatal side effect called PML, an untreatable brain infection caused by the JC virus that occurs in up to 1.3 percent of patients taking natalizumab.

The medication is typically prescribed in 300-milligram infusions every four weeks.

"There remains much unknown about whether the drug will lose effectiveness if dosing is extended," explains Dr. Zhovtis-Ryerson. "Our study showed treatment with natalizumab was safe for patients with similar efficacy reported as the standard dosing, potentially enabling patients to stay on effective MS medication at a reduced frequency of infusions and with lower risk of PML. "

Zhotvis-Ryerson and colleagues at 10 U.S. M.S. Centers sought to compare the safety and efficacy of an extended dose of natalizumab to the standard dose. They retrospectively compared 1,078 patients taking a standard 4-week dose to 886 taking an extended dose between 4 weeks, 3 days and 8 weeks, 5 days.

The researchers found extending the dosing schedule of natalizumab to between 5 and 8 weeks does not affect the drug's efficacy profile with 65 percent of participants in each group not showing clinical MS activity, and comparable rates of new lesions reported on imaging. Zero cases of PML were reported in the extended dosing group, while two cases were reported in the standard dose group, though the researchers said statistical significance has not been reached yet. No other major adverse events were reported.

"While the findings are encouraging, more research is needed to determine whether extending natalizumab dosing may reduce disability progression," says Dr. Zhovtis-Ryerson.

Natalizumab is manufactured by Biogen Idec and Elan, and sold under the name Tysabri.

More information: [P3.267] Safety and Efficacy of Extended Dose Natalizumab in Multiple Sclerosis: An Ongoing Multicenter Study. Session: P3: Poster Session III: MS and CNS Inflammatory Diseases: Treatment Efficacy, Safety and Tolerability (2:00 PM-6:30

PM)?Date/Time: Tuesday, April 21, 2015 - 2:00 pm

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