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Disease activity return during natalizumab treatment interruption in patients with multiple sclerosis.

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Abstract

BACKGROUND:

Due to a heightened risk of progressive multifocal leukoencephalopathy (PML) with increased natalizumab exposure, some physicians interrupt treatment of patients with multiple sclerosis (MS) despite a lack of data regarding the safety of treatment interruption, the rate and severity of MS disease activity return after treatment interruption, or alternative treatment strategies.

OBJECTIVES:

To determine the effects of natalizumab treatment interruption on clinical and MRI measures of disease activity in relapsing patients with MS.

METHODS:

Clinical relapses and gadolinium-enhanced (Gd+) lesions were analyzed over an 8-month period in patients from the AFFIRM, SENTINEL, and GLANCE studies of natalizumab, and their respective safety extension studies, following the voluntary suspension of natalizumab dosing that occurred in February 2005.

RESULTS:

Relapses were analyzed in 1,866 patients, and Gd+ lesions were analyzed in 341 patients. Annualized relapse rates and Gd+ lesions both increased shortly after natalizumab interruption and peaked between 4 and 7 months. A consistent return of disease activity was observed regardless of overall natalizumab exposure, whether or not patients received alternative MS therapies, and in patients with highly active MS disease. A rebound of relapse or Gd+ lesion activity, beyond placebo-treated levels from the clinical studies, was not observed in any of the analyses conducted.

CONCLUSIONS:

Following interruption of natalizumab treatment, MS disease activity returned in a pattern that was consistent with known pharmacokinetic and pharmacodynamic properties of natalizumab, and did not show evidence of rebound.

Comment in

- [Disease activity return during natalizumab treatment interruption in patients with multiple sclerosis.](#) [Neurology. 2011]
- [Interruption of natalizumab therapy for multiple sclerosis: what are the risks?](#) [Neurology. 2011]
- [What happens when natalizumab therapy is stopped?](#) [Expert Rev Neurother. 2011]

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