ACCLAIM: A randomized trial of abatacept (CTLA4-Ig) for relapsing-remitting multiple sclerosis.

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Abstract

BACKGROUND:

Costimulatory blockade of T lymphocytes with the CTLA4-Ig fusion protein abatacept could be an effective treatment for the immune-mediated neuroinflammatory disease relapsing-remitting multiple sclerosis (RRMS).

OBJECTIVE:

To evaluate efficacy and safety of abatacept in RRMS.

METHODS:

ACCLAIM (A Cooperative Clinical Study of Abatacept in Multiple Sclerosis) was a Phase II, randomized, double-blind, placebo-controlled, multi-center trial. In all, 65 of 123 planned participants with RRMS were randomized to monthly intravenous infusions of abatacept or placebo for 24 weeks in a 2:1 ratio, switched to the opposite treatment at 28 weeks, and received their final dose of study medication at 52 weeks. Enrollment was closed early due to slow accrual. The primary endpoint was the mean number of new gadolinium-enhancing (Gd+) lesions obtained on magnetic resonance imaging (MRI) scans performed every 4 weeks.

RESULTS:

No statistically significant differences were observed in mean number of new Gd+ MRI lesions between the abatacept and placebo groups. No statistically significant differences were observed in other MRI and clinical parameters of RRMS disease activity. Abatacept was well tolerated.

CONCLUSION:

The ACCLAIM study did not demonstrate efficacy of abatacept in reducing the number of new Gd+ MRI lesions, or clinical measures of disease activity in RRMS.

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KEYWORDS:

Abatacept; autoimmune diseases; clinical trial; costimulatory and inhibitory T-cell receptors; gadolinium; intervention study; magnetic resonance imaging; multiple sclerosis; relapsing-remitting

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