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# Intravenous immunoglobulin treatment following the first demyelinating event suggestive of multiple sclerosis: a randomized, double-blind, placebo-controlled trial.

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**BACKGROUND:** Intravenous immunoglobulin (IVIg) has been reported to reduce disease activity in patients with relapsing-remitting multiple sclerosis. We assessed the effect of IVIg treatment in patients after the first neurological event suggestive of demyelinating disease and evaluated the occurrence of a second attack and dissemination in time demonstrated by brain magnetic resonance imaging within the first year from onset. **METHODS:** We conducted a randomized, placebo-controlled, double-blind study in 91 eligible patients enrolled within the first 6 weeks of neurological symptoms. Patients were randomly assigned to receive IVIg treatment (2-g/kg loading dose) or placebo, with boosters (0.4 g/kg) given once every 6 weeks for 1 year. Neurological and clinical assessments were done every 3 months, and brain magnetic resonance imaging was performed at baseline and the end of the study. **RESULTS:** The cumulative probability of developing clinically definite multiple sclerosis was significantly lower in the IVIg treatment group compared with the placebo group (rate ratio, 0.36 [95% confidence interval, 0.15-0.88];  $P = .03$ ). Patients in the IVIg treatment group had a significant reduction in the volume and number of T2-weighted lesions and in the volume of gadolinium-enhancing lesions as compared with the placebo group ( $P = .01$ ,  $P = .01$ , and  $P = .03$ , respectively). Treatment was well tolerated, compliance was high, and incidence of adverse effects did not differ significantly between groups. **CONCLUSIONS:** Intravenous immunoglobulin treatment for the first year from onset of the first neurological event suggestive of demyelinating disease significantly lowers the incidence of a second attack and reduces disease activity as measured by brain magnetic resonance imaging.

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