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Medical Update Memo

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Cross-sectional study assessing long-term safety of interferon-{beta}-1b for relapsing-remitting MS

Summary

A 16-year long-term interferon-beta-1b (IFNbeta-1b) follow-up has been performed to understand clinical, MRI, cognitive and patient-reported outcomes. The authors followed 372 people with MS taking IFN-beta subcutaneously every other day for up to five years. Sixteen years later people were asked to participate in this follow-up study. **Reder AT, Ebers GC, Traboulsee A, Li D, Langdon D, Goodin DS, Bogumil T, Beckmann K, Konieczny A; For the Investigators of the 16-Year Long-Term Follow-Up Study. Neurology. 2010 Jun 8;74(23):1877-1885.**

Details

In the pivotal study, 372 patients were randomized to placebo (n = 123), IFNbeta-1b 50 microg (n = 125), or IFNbeta-1b 250 microg (n = 124) subcutaneously every other day for up to 5 years. Sixteen years later, patients were asked to participate in this cross-sectional follow-up study. No particular therapy was stipulated during follow-up. Adverse events experienced since the pivotal trial were recorded. Neutralizing antibodies (NAbs) to IFNbeta-1b were measured using the myxovirus protein A induction assay. Statistical analyses were descriptive.

In total, 88.2% of patients (328/372) were identified. Some centers achieved 100% ascertainment, obviating selection bias. Treatment-related adverse events (e.g., leukopenia and liver and thyroid dysfunction) reported by LTF participants were in keeping with those previously established. Based on a follow-up period that includes 2,000 patient-years of IFNbeta-1b treatment, no new adverse events were observed that were associated with long-term IFNbeta-1b exposure. By LTF, NAbs to IFNbeta-1b disappeared in the majority (76%) of NAb-positive patients. NAb status during the pivotal study appeared to have no impact on long-term clinical and MRI outcomes. There were

more deaths among patients assigned to placebo in the pivotal study (20/109 [18.3%]) compared with patients who received IFNbeta-1b 50 microg (9/108 [8.3%]) or IFNbeta-1b 250 microg (6/111 [5.4%]).

CONCLUSION: The results from the 16-Year Long-Term Follow-Up study support the long-term safety of interferon-beta-1b therapy in multiple sclerosis.

CLASSIFICATION OF EVIDENCE: This study provides Class III evidence that patients with relapsing-remitting MS taking IFNbeta-1b 50 microg or 250 microg subcutaneously every other day for up to 5 years, with subsequent unspecified treatment, have fewer deaths after 16 years of follow-up than similar patients on placebo for up to 5 years, with subsequent unspecified treatment (risk difference 11.5%, 95% confidence interval 4-19).

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