MULTIPLE SCLEROSIS

Pegylated IFN- β 1a could lessen patients' injection burden

Patients with MS treated with long half-life pegylated IFN- β 1a once every 2 or 4 weeks have significantly reduced relapse rates compared with patients receiving placebo treatment, according to a new study published in *The Lancet Neurology*.

"IFN- β therapies are well-established treatments for MS, and considered to be safe and effective," explains lead investigator Peter Calabresi. "But IFN- β molecules are small proteins rapidly cleared by the kidneys, meaning that treatment requires frequent injections—at least weekly." Common adverse effects, such as flu-like symptoms and injection-site pain, might negatively impact patients' quality of life and discourage treatment adherence.

Pegylation—adding an inert polyethylene glycol side chain to a molecule—has previously been shown to extend the half-life of IFN- β 1a and increase systemic exposure to the drug without changing its biological effects. Subcutaneous pegylated IFN- β 1a might therefore control disease activity with less-frequent administration than conventional intramuscular interferon.

Calabresi and colleagues randomly assigned 1,512 patients with relapsing–remitting MS to receive subcutaneous injections of pegylated IFN- β 1a once every 2 weeks or once every 4 weeks, or to receive placebo injections.

After 48 weeks of treatment, the annualized relapse rates in the groups receiving pegylated IFN- β 1a (0.256 in the group treated every 2 weeks, and 0.288 in the group treated every 4 weeks) were significantly lower than in the placebo group (0.397).

The researchers also reported that patients receiving pegylated IFN- β 1a were less likely to have sustained disability progression than patients receiving placebo.

Pegylated IFN- β 1a also decreased the likelihood of new or newly enlarging brain lesions.

"These findings demonstrate that the benefits provided by existing interferon therapies for MS can be retained while at least halving the injection burden associated with the treatment," summarizes Calabresi.

“ Pegylated IFN- β 1a could be an important addition to the MS armamentarium... ”

For the remainder of the 2-year trial, the patients who had received placebo treatment were randomly reassigned to receive pegylated IFN- β 1a every 2 or every 4 weeks. The investigators plan to present the final results from the trial later this year, which should further elucidate the efficacy and safety profiles of the treatment regimens.

Although the benefits of pegylated IFN- β 1a in the present study were reported to be consistent with those of existing IFN- β treatments, additional trials are needed to establish the relative efficacy of pegylated versus conventional IFN- β s as first-line interventions for relapsing–remitting MS.

Overall, the results suggest that disease activity in MS can be controlled without burdensome weekly injections. "Pegylated IFN- β 1a could be an important addition to the MS armamentarium given the favorable dosing schedule," concludes Calabresi.

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Original article Calabresi, P. A. *et al.* Pegylated interferon beta-1a for relapsing-remitting multiple sclerosis (ADVANCE): a randomised, phase 3, double-blind study. *Lancet Neurol.* doi:10.1016/S1474-4422(14)70068-7