MULTIPLE SCLEROSIS

Glatiramer acetate delays symptom progression

A drug approved for the treatment of relapsing–remitting multiple sclerosis can delay the onset of symptoms in patients with early signs of the disease. Results of a randomized, double-blind, placebo-controlled trial show that "glatiramer acetate reduces the risk of developing clinically definite multiple sclerosis by 45%," says chief investigator Giancarlo Comi, of the University Vita-Salute, Milan, Italy.

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Glatiramer acetate is used to reduce the frequency of relapses in patients with relapsing–remitting multiple sclerosis. Comi and colleagues assessed the efficacy and tolerability of early treatment with glatiramer acetate in delaying the onset of multiple sclerosis in patients with clinically isolated syndrome (CIS). Patients with this syndrome, defined as a neurological attack lasting at least 24 h, do not meet the criteria for a diagnosis of multiple sclerosis; however, CIS is the first clinical event experienced by almost all individuals eventually diagnosed as having multiple sclerosis. Clinical and MRI evidences suggest that early treatment can prevent or delay accumulation of irreversible neuronal damage in this patient group.

The multicenter trial enrolled 481 patients presenting with a CIS from 16 countries worldwide. Patients received daily treatment with either 20 mg of subcutaneous glatiramer acetate ($n = 243$) or placebo ($n = 238$) for up to 36 months, unless they developed clinically definite multiple sclerosis (characterized by a second neurological attack).

Compared with the placebo group, patients treated with glatiramer acetate had a 45% reduction in risk of converting to clinically definite multiple sclerosis. Of the patients who converted, time to clinically definite multiple sclerosis was more than doubled, from 336 days for placebo to 722 days for glatiramer acetate.

Further to the findings that glatiramer acetate efficaciously prevents or delays progression from CIS to multiple sclerosis, the drug showed favorable tolerability, establishing glatiramer acetate as a suitable early treatment option for patients with CIS. "The accumulated evidence from previous studies in relapsing–remitting multiple sclerosis and from this study in patients [with CIS] suggests that glatiramer acetate reduces the frequency of relapses in the short term and may reduce the rate of accumulation of irreversible disability in the long term," notes Comi.

The data from this study were presented at the 2008 Annual Meeting of the American Academy of Neurology and have been submitted to the regulatory authorities in the US and in Europe. As a result, glatiramer acetate has been approved for the treatment of patients with CIS who have a high risk of developing multiple sclerosis.

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Original article Comi, G. *et al.* Effect of glatiramer acetate on conversion to clinically definite multiple sclerosis in patients with clinically isolated syndrome (PreCISe study): a randomised, double-blind, placebo-controlled trial. *Lancet* **374**, 1503–1511 (2009).