

Medical Update Memo

October 20, 2009

PreCISe Study Results – Showing Benefit of Copaxone® in People at High Risk for MS

Summary

Results of the PreCISe Study – which showed that early treatment with Copaxone® (glatiramer acetate, Teva Pharmaceutical Industries) delayed the development of definite multiple sclerosis – have now been published. Dr. Giancarlo Comi (Scientific Institute San Raffaele, Milan) and colleagues presented results of this study at the Annual Meeting of the American Academy of Neurology in 2008, and based on these results, Health Canada has extended the labeling of Copaxone to include people with MS who have experienced a first clinical episode and have MRI features consistent with MS. The team's report has now been published in the Lancet (**published online October 7, 2009**)

Details

Background: The diagnosis of clinically definite MS requires two neurological events suggesting demyelination (loss of nerve-fiber insulation) in the brain and spinal cord separated in time and in location in the nervous system. Studies have shown that individuals who experience a clinically isolated syndrome (a single occurrence of a sign or symptom of demyelination) and multiple clinically “silent” MRI-detected brain lesions are at high risk for developing clinically definite MS within several years. Individuals who have similar neurologic problems but no evidence of MRI-detected lesions are at relatively low risk for developing MS over the same time period.

The PreCISe Study: A total of 481 people with CIS with lesions typical of MS on brain MRIs were randomly assigned to receive either Copaxone (given by daily under-the-skin injections) or inactive placebo for up to 36 months. The primary outcome measure was the time it took individuals to experience a second attack that would confirm the diagnosis of definite MS.

Results showed that in those who took Copaxone, the risk of developing clinically definite MS was reduced by 45% versus placebo, and the time to development of definite MS was delayed by 386 days more than in the placebo group. The proportion of individuals who developed MS was 43% in the placebo group versus 25% in the Copaxone group. At a pre-planned interim analysis, the Data Monitoring Committee recommended that all people in the placebo-controlled group be offered Copaxone treatment.

In a post-study analysis based on all patients who completed two years of the study without developing MS, there was a significant reduction in new “T2” lesions in those who took Copaxone versus those who took placebo, by 43% during the first year and by 52% over the entire two years. (T2-weighted MRI scans are used to provide information about the total amount of tissue damage in the brain or spinal cord.)

The most common adverse events were consistent with those known to be associated with Copaxone use: injection-site reactions (56% in the Copaxone group and 24% in the placebo group) and immediate post-injection reactions (19% in the Copaxone group and 5% in the placebo group). Fourteen people in the Copaxone group and four in the placebo group withdrew from the study because of adverse events.

National Research and Programs

Offert en français.

Disclaimer

The Multiple Sclerosis Society of Canada is an independent, voluntary health agency and does not approve, endorse or recommend any specific product or therapy, but provides information to assist individuals in making their own decisions.