Multiple Sclerosis Society of Canada
Société canadienne de la sclérose en plaques

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Medical Update Memo

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Clinical trial for oral Lipitor still enrolling participants for study

SUMMARY
Investigators - including those at one centre in Canada - are still enrolling participants for a clinical trial evaluating the effects of oral Lipitor® (atorvastatin) compared with inactive placebo in 152 people at high risk for developing MS. Previous studies have suggested that cholesterol-lowering "statins" can alter immune responses in a way that may hold promise in treating MS. The mechanism underlying the drug's possible promise for MS appears to be immune system modulation, rather than a cholesterol-lowering mechanism.

DETAILS
Investigators at 14 MS centres in the North America - including one centre in Canada - are conducting a clinical trial evaluating the effects of oral Lipitor® (atorvastatin), compared with inactive placebo in 152 people at high risk for developing MS. The study is supported by the Immune Tolerance Network, a research consortium funded by the NIH's National Institute of Allergy and Infectious Diseases (USA). The lead investigators are Scott Zamvil, MD, PhD, and Emmanuelle Waubant, MD, PhD, of the University of California, San Francisco.

Previous studies have suggested that cholesterol-lowering "statins" can alter immune responses in a way that may hold promise in treating MS. A report in Nature (November 7, 2002) found that Lipitor prevented or reversed the MS-like disease EAE in mice. In addition, a small open-label pilot study by Timothy Vollmer, MD, and colleagues in 28 people with relapsing-remitting MS found that the cholesterol-lowering pill Zocor® (simvastatin) safely reduced the number of new lesions (Lancet, May 15, 2004). The mechanism underlying the drug's possible promise appears to be immune system modulation, rather than a cholesterol-lowering mechanism.

The primary objective of the study is to evaluate the effects of Lipitor to decrease or delay clinical and MRI disease activity. Secondary objectives are to determine if Lipitor is safe in people with CIS, to determine which immune system cells or molecules are modified by Lipitor, to evaluate the effects of Lipitor on brain tissue loss, and to determine potential residual benefits after the discontinuation of therapy.

Eligibility for participation: People eligible for participation include individuals 18-55 years of age with no previous neurological history, who experience a clinically isolated syndrome (CIS, a single demyelinating event, for example, an attack of optic neuritis in one eye, or an episode of numbness on one side) lasting at least 48 hours and magnetic resonance imaging findings suggestive of MS. Participants must receive a three-to five-day course of corticosteroids starting within 60 days of onset of a CIS and must be enrolled within 90 days of onset of a CIS.

For more information, contact: MS Clinic, Montreal Neurological Institute
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(With information from the National MS Society (USA)

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