



Multiple
Sclerosis
Society of
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Medical Update Memo

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Small Edmonton-based clinical trial shows some slowing of disease progression

SUMMARY

A small phase II study by researchers at the University of Alberta has found that the administration of an experimental drug called MBP8298 may slow the progression of multiple sclerosis in some participants who have progressive forms of MS and who have specific immune response genes. The findings were published in the June 13, 2006 online version of the *European Journal of Neurology*. A large, multi-centre phase III study is now underway.

DETAILS

As reported in the June 13, 2006 online version of the *European Journal of Neurology*. Dr. Kenneth Warren and Ingrid Catz found the administration of the experimental drug MBP8298 delayed the progression of MS in a subgroup of study participants for five years compared to the group that received a placebo (non-active substance). The researchers developed MBP8298 at the University of Alberta.

A total of 32 people with progressive MS (either secondary-progressive or primary-progressive) were given MBP8298 or placebo intravenously (into a vein) every six months for two years in this double-blind study (neither the participants nor the examining physicians knew who was receiving active drug or placebo). The participants ranged from 3.0 (able to walk without assistance) to 7.5 (can walk a few steps but needs a wheelchair for mobility) on the standard Expanded Disability Status Scale (EDSS). The overall result was that there was no significant difference in progression between those who received MBP8298 and those who received placebo.

When a subgroup analysis was done taking into account the participants' immune response genes, the investigators found people with HLA haplotypes HLA-DR2 or HLA-DR4 showed a statistically significant benefit of MBP8298 treatment compared to participants with the same haplotypes who received placebo. HLA-DR2/DR4 haplotypes are found in 50-70 percent of people with MS compared to 20-30 percent of the general population.

The researchers also measured whether MBP8298 suppressed antibodies to myelin basic protein to determine the level of immune tolerance. They found antibody suppression in most MBP8298 treated participants, but antibody suppression was not predictable of any clinical benefits.

MBP8298 is a synthetic peptide that corresponds to a portion of the body's own myelin basic protein, one of the proteins that make up myelin, the vital protective covering of nerves in the central nervous system. This sequence is thought to be the main target of immune system cells during MS attacks. By administering MBP8298, the researchers hope to restore immune tolerance of this important myelin component.

A phase II/III clinical trial of the use of MBP8298 in the treatment of secondary-progressive MS is currently enrolling participants in Canada, the United Kingdom, Denmark and Sweden. Approximately 550 participants will receive either MBP8298 or placebo intravenously every six months for two years. BioMS, an Edmonton-based biotechnology company, is sponsoring the study. For more information about the study, see the BioMS website: www.biomsmedical.com

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