New Multiple Sclerosis Drug May Reverse Nerve Damage

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An experimental drug that may reverse demyelination of nerves in multiple sclerosis (MS) patients has been deemed safe and tolerable in a Phase I clinical trial.

Published online August 27, 2014, in *Neurology, the study evaluated the safety of the* monoclonal antibody, BIIB033, which blocks the central nervous system (CNS) protein LINGO-1 that prevents myelination. Although current MS treatments seek to reduce new damage to the brain, they do not repair new or previous damage.

The study evaluated BIIB033 in 47 patients with relapsing-remitting MS (RRMS) or secondary-progressive MS (SPMS) who were given either 2 doses of the drug 2 weeks apart or placebo. Additionally, 72 healthy subjects received either placebo or 1 dose of BIIB033 by injection. Both arms of the trial received varying amounts of the drug, from 0.1 to 100 mg/kg.

Reported side effects of headaches, upper respiratory infections, and urinary tract infections were similar among those who received BIIB033 and those who received placebo, with no serious adverse events or deaths. The side effects were labeled as mild to moderate and determined to be unrelated to the drug.

Though the treatment was found to be safe, its ability to enhance remyelination still needs to be examined in future trials. Due to MS patients' immune systems attacking myelin that insulates the nerves in the CNS, current drugs seek to decrease inflammation through modulation of the immune system with an undetermined impact on the chronic disease course.

In an accompanying commentary, Pedro Brugarolas, PhD, and Brian Popko, PhD, wrote that promoting myelin repair might be more effective in reducing long-term disability for MS patients than commonly used current treatments. The commentary noted that the biggest challenge for bringing myelin repair therapies to the clinic is accurately monitoring a treatment's efficacy in preserving the integrity of the myelin.

"The anti-LINGO-1 trial is likely the first of many that will test drugs that have been shown to enhance remyelination in murine models," the commentary stated. "Soon, we should know whether this approach will provide benefit to patients with MS, which would be the first evidence that enhancing myelin repair may alter the course of this disease. Although the jury is still out on the Phase II trial, the Phase I verdict is promising."

A Phase II trial for BIIB033 is set to be conducted in combination with the front-line, anti-inflammatory interferon therapy, Avonex. That study will evaluate whether the combined treatment provides a benefit that is equal to riskier, yet more potent, anti-inflammatories that are currently used when front-line therapies are deemed ineffective.

“With these results, we have been able to start Phase II studies to see whether this drug can actually repair the lost myelin in humans and have any effect on restoring physical and cognitive function and improving disability,” said study author Diego Cadavid, MD, of Biogen Idec.