Use of drug reduces likelihood of progression to multiple sclerosis

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People who received injections of the multiple sclerosis (MS) drug interferon beta-1a soon after their first signs of possible MS were less likely to progress to clinically definite MS than people who switched to interferon beta-1a from placebo, according to new phase three results of the three-year REFLEXION clinical trial that will be presented as part of the Emerging Science program (formerly known as Late-Breaking Science) at the American Academy of Neurology's 64th Annual Meeting in New Orleans, April 21 to April 28, 2012.

The trial was conducted with the human serum albumin-free formulation of interferon beta-1a, which is now available in all European Union countries, Australia, Canada and Switzerland, as well as a number of countries in Asia, Latin America, Africa and the Middle East. It is not available in the United States.

"While we've known it's beneficial to start MS drugs as soon as possible, this is the first trial to show a benefit of early injections of interferon beta-1a treatment at three years," said Mark Freedman, MD, with the University of Ottawa in Ontario, Canada, and a Fellow of the American Academy of Neurology.

The three-year clinical trial involved 517 people who had experienced a first clinical episode suggestive of a demyelinating event, such as tingling, numbness, muscle weakness or problems with balance, along with having at least two clinically silent brain lesions detected by a brain MRI scan.

For two years, one-third of the participants received 44 mcg of interferon beta-1a subcutaneously three times a week; one-third received 44 mcg of the drug once a week, which is an unapproved dosage; and another one-third received placebo for two years or until experiencing a second clinical episode, at which point they were switched to three-times-weekly dosing. After the two years were over, the 133 people who were still receiving the placebo were switched to the three-times-weekly dose and the others continued their originally allocated dosages. The participants started their treatment an average of 58 days after their first symptoms.

After the third year of the study, the researchers found that those who had been receiving the drug three times a week or once a week for the duration of the trial were less likely to be diagnosed with clinically definite MS (defined as having a second clinical attack or a sustained increase in the Expanded Disability Status Scale disability score of greater than 1.5) than those who had initially received the placebo. The cumulative probability of being diagnosed with clinically definite MS by the end of the third year was 41 percent for the delayed treatment group (people who had switched from placebo to three-times-weekly treatment), 28 percent for those who had received once-a-week treatment all three years, and 27 percent for those who had three-times-weekly treatment for three years.

The study also found that those who had received the treatment for the full three years were less likely to meet the McDonald criteria for a MS diagnosis, a different measure than the one for clinically definite MS that includes an evaluation of MRI. A total of 87 percent of people who had switched from placebo to the treatment after two years met the McDonald criteria for MS after three years, compared with 79 percent of those who had received the weekly treatment and 67 percent of those who had treatments three times a week.

"While doses three times a week and once a week equally delayed a clinically definite MS diagnosis without MRI measures, there were significantly more benefits in taking the drug three times a week compared with once a week when it came to brain lesion changes and other McDonald criteria for diagnosing MS," said Freedman.

The REFLEXION trial is ongoing and will provide long-term data out to five years.

The most common adverse events in the trial were flu-like symptoms, injection site reactions and headache.

Provided by American Academy of Neurology