

## Study revisits first clinical trial to treat multiple sclerosis decades later

April 22 2011



This graph shows that data gathered 21 years after the original trial ended shows a significant long-term survival advantage for people who received injections of interferon beta-1b (blue line) over people who received placebo (black line).

(Medical Xpress) -- Tracking down nearly all 372 multiple sclerosis patients involved in a pivotal clinical trial of a drug decades ago has allowed a group of researchers from several institutions, led by professors at the University of California, San Francisco (UCSF) and the



University of Chicago, to a surprising discovery.

The clinical trial, conducted in the late 1980s, involved the biotech drug interferon beta-1b – an injectable protein that in 1993 became the first pharmaceutical approved by the U.S. Food and Drug Administration for treating multiple sclerosis.

Now, more than two decades later, the researchers are reporting that the people who received interferon in the trial, as opposed to a placebo, were only about half as likely to have died in the decades since.

"This is a very significant reduction in mortality," said UCSF neurologist Douglas Goodin, MD, who presented a poster on the study last week with his coauthor Anthony Reder of the University of Chicago at the 63rd Annual Meeting of the American Academy of Neurology in Hawaii.

Clearly there is something profound reflected in the data, the study authors said, but they could not say what exactly accounts for the difference. After all, the study was over by the early '90s and in the decades since all of the patients likely took drugs other than interferon beta-1b, since within a decade three other drugs also were approved for treating MS.

## A Disease of the Nervous System

Multiple sclerosis is an autoimmune disease that causes recurrent attacks on the nervous system, inducing inflammatory lesions in the brain. These lesions sometimes cause people with MS to become temporarily blind or lose control of their bladders. Often the lesions disappear and the person with MS recovers – until the next attack.

"It doesn't always get better," said Goodin, director of the Multiple



<u>Sclerosis</u> Center at UCSF Medical Center. "Over time people may become permanently disabled because of these lesions."

Interferon beta-1b works by exerting an anti-inflammatory effect yet, even though it has been around for many years now, there have never been any long-term studies of its effect on human health.

What the new data indicate, said Goodin and Reder, is significant longterm survival advantage to taking the drug. Now they are investigating possible biological explanations of this difference.

The presentation "Mortality Outcomes for Interferon Beta-1b vs Placebo 21 Years Following Randomization" was authored by Douglas Goodin, Anthony Reder, George Ebers, Gary Cutter, Marcelo Kremenchutzky, Joel Oger, Dawn Langdon, Mark Rametta, Karola Beckmann, and Volker Knappertz. Authors are from the original 11 North American clinical trial sites and Bayer Pharmaceuticals.

Provided by University of California, San Francisco

Citation: Study revisits first clinical trial to treat multiple sclerosis decades later (2011, April 22) retrieved 28 April 2024 from https://medicalxpress.com/news/2011-04-revisits-clinical-trial-multiple-sclerosis.html

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