

# Risk of leukemia with multiple sclerosis drug higher than thought

April 30 2009

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The risk of developing leukemia as a side effect of a drug for multiple sclerosis (MS) is higher than previously reported, according to a study to be presented as part of the Late-breaking Science Program at the American Academy of Neurology's 61st Annual Meeting in Seattle, April 25 - May 2, 2009.

Mitoxantrone is an immunosuppressant drug approved by the FDA for treatment of several forms of advancing MS. It is one of only two drugs that has been shown to benefit people with secondary progressive MS who are having attacks. However, the drug can cause heart damage at high total doses. Due to this, the lifetime cumulative dose is equal to about eight to 12 doses over two to three years.

Previous studies have also shown that the people with MS treated with the drug have an increased risk of developing leukemia. Those studies showed that acute leukemia occurred in .07 percent to .25 percent of MS patients taking mitoxantrone. Today's retrospective study of 2,854 Italian people with MS receiving the drug found that leukemia occurred in .74 percent.

"This rate is significantly higher than what has been previously reported," said study author Vittorio Martinelli, MD, of University Vita-Salute in Milan, Italy. "The potential risk of leukemia should be carefully considered against the potential benefits of mitoxantrone treatment on every single patient."

The study participants all had at least one cycle of mitoxantrone treatment and were observed for at least one year. A total of 21 people developed leukemia, eight of whom died. The people who developed leukemia had more treatment cycles than those who did not develop leukemia—8.6 cycles versus 7.2 cycles. They also had a greater cumulative dose of mitoxantrone.

The leukemia occurred an average of three years after the first use of the drug and an average of 18 months after the end of treatment.

"It is vital that all MS patients treated with mitoxantrone undergo prolonged and careful hematological follow-up to check for acute leukemia," Martinelli said.

The American Cancer Society has estimated there were 44,270 new cases of [leukemia](#) in the general U.S. population last year.

Source: American Academy of Neurology ([news](#) : [web](#))

Citation: Risk of leukemia with multiple sclerosis drug higher than thought (2009, April 30) retrieved 12 May 2024 from <https://medicalxpress.com/news/2009-04-leukemia-multiple-sclerosis-drug-higher.html>

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