

Medicare claims show long-term prostate cancer prevention benefits of finasteride

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Men who take the medication finasteride get a prostate cancer prevention benefit that can last 16 years - twice as long as previously recorded, according to SWOG clinical trial analysis published in the *Journal of the National Cancer Institute*.

This finding was made possible by a new research strategy - linking Medicare claims data to [clinical trial data](#), in this case from a landmark study run by SWOG, the federally funded cancer clinical trial network. The SWOG study, known as the Prostate Cancer Prevention Trial, or PCPT, set out to see whether finasteride, a drug used to treat symptoms of [prostate](#) enlargement as well as male pattern baldness, would prevent [prostate cancer](#) in men over the age of 55. The study enrolled 18,882 men from 1993-1997. It was stopped in 2003 when investigators learned that finasteride reduced [prostate cancer risk](#) by 25 percent when compared with a placebo. SWOG leader Ian Thompson, Jr., MD, of CHRISTUS Santa Rosa Hospital Health System, was the study chair of PCPT.

Joseph Unger, PhD, a SWOG biostatistician and health services researcher from Fred Hutchinson Cancer Research Center, has a track record of using new research methods to answer bigger, bolder questions about cancer prevention and treatment. Along with SWOG colleague Dr. Dawn Hershman, Unger has pioneered for a decade the use of secondary sources of data, such as Medicare claims, U.S. Census Bureau data, and public health statistics from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program, to examine new

hypotheses.

For this study, Unger wanted to know if the protective effects of finasteride lasted longer than seven years - the amount of follow-up evaluated in the PCPT. Answering this question would typically require reopening the old study, reconnecting with patients, and conducting extensive follow-up - an expensive and time-consuming proposition. But Unger took another tack, requesting and obtaining a data use agreement from the federal Centers for Medicare & Medicaid Services to access to records from Medicare, the health insurance program for people over 65.

Using patient information from the PCPT, Unger linked patients enrolled in the PCPT to their Medicare claims from 1999 through 2011. The team was surprised to find they were able to successfully link 75 percent of PCPT trial participants. Unger and colleagues at Fred Hutch created an algorithm to flag a prostate cancer diagnosis in the Medicare data, and examined the diagnoses over time. The team identified 3,244 PCPT participants who were later diagnosed with prostate cancer over a median follow-up of 16 years, and found that participants on the PCPT that took finasteride had a 21 percent decreased risk of getting prostate cancer, compared to those who took a placebo drug, over the course of those 16 years.

"These findings raise the intriguing possibility that seven years of [finasteride](#) can reduce prostate cancer diagnoses over a much longer period than was previously shown," Unger said. "It's a low-cost generic drug, with minimal side effects, that can have a benefit that lasts long after men stop taking it."

At the same time, Unger said, the SWOG study shows the value of using Medicare claims to extend follow-up for trial participants and answer new questions about cancer care and prevention. "These secondary data

sources are emerging as a new paradigm for long-term follow up for [cancer clinical trials](#)," he said. "It's an exciting new avenue of research."

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Provided by SWOG

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