Prostate Cancer Prevention Trial identifies men mostly likely to undergo challenging study procedure

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Healthy men participating in the Prostate Cancer Prevention Trial who actively participate in all steps of the clinical trial are most likely to undergo a biopsy, according to a study published in *Cancer Epidemiology, Biomarkers and Prevention* – a journal of the American Association for Cancer Research.

The Prostate Cancer Prevention Trial was a randomized, double-blind, placebo-controlled trial which tested the efficacy of finasteride, a drug used for prostate cancer prevention. This study was conducted by SWOG – a cancer research cooperative group that designs and conducts multidisciplinary clinical trials.

Researchers at The University of Texas MD Anderson Cancer Center and the Fred Hutchinson Cancer Research Center used a systematic model to identify factors associated with men adhering to the end-of-study (EOS) biopsy requirement of the trial. The EOS biopsy, an invasive procedure that examines the cells or tissues of the prostate gland to determine if cancer is evident, is an important part of the study.

"Our study is unique because it evaluated factors prospectively associated with an invasive biopsy for a cancer prevention trial, not a cancer treatment trial," said Ellen R. Gritz, Ph.D., chair of Behavioral Science at MD Anderson, and lead author on the study.

The prevention trial was coordinated by SWOG at 219 sites involving more than 18,000 men. Participants were randomized into one of two groups; those administered finasteride and those given a placebo. Participants received educational materials about the study and biopsy procedures and were asked to attend regularly scheduled appointments throughout the trial.

Funded by the National Cancer Institute, scientists analyzed healthy men over a seven-year period to identify which factors at the six-year study mark were associated with the willingness of the participant to undergo a biopsy. The factors examined included psychosocial outcomes, participant health status, participant adherence, and characteristics of the clinical sites at which the study was conducted.

"The biopsy provided the biological specimens that could be tested to see if a man's prostate cells were cancer-free after seven years on the trial," said Carol Moinpour, Ph.D., of the Fred Hutchinson Cancer Research Center. "That is, the biopsy provided definitive information about which men had prostate cancer seven years after the study started."

Researchers were able to assess factors associated with adherence for more than 13,000 men from the trial, and analyzed factors based on whether or not study participants had been prompted for a clinical biopsy by year six of the study.

Researchers found participants were more likely to adhere to the EOS biopsy if one year prior to the biopsy they were adherent to the study drug, kept appointments and underwent required tests and were in good health. Participants who had an EOS biopsy were more likely to be adherent to the study drug at year six – 84 percent. Among participants who were not biopsied, only 47 percent were adherent to the study drug. Results also showed that 98 percent of men who had an EOS biopsy had

the DRE (digital rectal exam) or PSA test done at year six, compared to 75 percent of men who did not have the EOS biopsy.

"We also found that participants were more likely to adhere to biopsies if the study site that recruited the participant enrolled more than 200 participants and/or had resources for conducting activities to encourage continued participation in the trial," said Gritz.

Researchers said monitoring adherence behaviors in clinical trial participants can help identify participants at risk for noncompliance to a study requirement, and help create a model for adherence intervention strategies in future trials.

"If we are able to determine which factors are associated with good adherence to study regimens evaluating cancer prevention agents, we may be able to improve the conduct of such large trials by targeting interventions to boost adherence," said Gritz.

Provided by University of Texas M. D. Anderson Cancer Center