

RANDOMIZED TRIAL FINDS DRUG THERAPY REDUCES HOT FLASHES DURING PROSTATE CANCER TREATMENT

February 2, 2026 – A national clinical trial led by the Alliance for Clinical Trials in Oncology has found that oxybutynin, a drug often used to treat overactive bladder symptoms, reduces hot flashes compared to the placebo in men receiving hormone therapy for prostate cancer. This primary analysis of Alliance A222001 is published in the [Journal of Clinical Oncology](#).



“Oxybutynin demonstrated clear and clinically meaningful improvements in both hot flash frequency and quality of life for men undergoing hormone therapy for prostate cancer,” said Bradley J. Stish, MD, the study’s lead investigator and a radiation oncologist at the Mayo Clinic. “These results provide strong support for its use as an effective management option for this challenging and often overlooked side effect of prostate cancer treatment.”

Androgen-deprivation therapy (ADT) is an effective treatment against prostate cancer as it lowers male hormones like testosterone needed to fuel cancer cells. However, ADT causes hot flashes in up to 80 percent of the men who take it, leading to fatigue, sleep disturbances and reduced quality of life, often leading patients to discontinue ADT due to the side effects.

The Phase II randomized, double-blind, placebo-controlled trial evaluated whether two doses of oxybutynin (2.5 mg twice daily and 5 mg twice daily) could improve hot flash symptoms compared with placebo over six weeks. The study enrolled 88 men from 15 academic and community cancer centers; 81 participants were eligible for final analysis. The average age of the participants was 68.5.

In this trial, both doses of oxybutynin substantially improved hot flash symptoms compared to the placebo over the six-week treatment period. Men receiving placebo experienced an average reduction of 2.15 hot flashes per day and a 4.85-point drop in daily hot flash severity scores, whereas those taking 2.5 mg of oxybutynin twice daily reported reductions of 4.77 hot flashes per day and a 9.94-point decrease in severity, and those receiving 5 mg twice daily experienced the largest improvements, with 6.89 fewer hot flashes per day and a 13.95-point reduction in severity.

Improvements occurred quickly, often during the first week of treatment, and were sustained throughout the study. The proportion of patients achieving at least a 50 percent reduction in hot flash scores was also markedly higher with oxybutynin: 57 percent in the 2.5 mg group and 79 percent in the 5 mg group, compared with 32 percent taking placebo. Treatment was well tolerated overall. Dry mouth was the most common side effect reported.

“These results are incredibly encouraging,” added Dr. Stish. “Men with hot flashes from hormone therapy now have another therapeutic option available to help reduce their symptom burden. Future research will look to further our understanding of hot flash therapy options in this patient population.”

In addition to the Mayo Clinic in Rochester, MN, investigators on the study included scientists from the Alliance Protocol Operations in Chicago, IL; Alliance Statistics and Data Management Center at the Mayo Clinic in Scottsdale, AZ; Aspirus Regional Cancer Center in Wausau, WI; Ellis Fischel Cancer Center in Columbia, MO; Georgetown-Lombardi Comprehensive Cancer Center, Washington, DC; Gibbs Cancer Center in Spartanburg, SC; Mayo Clinic Division of Nursing in Jacksonville, FL; Sandra and Edward Meyer Cancer Center at Weill Cornell Medicine in New York, NY; SCOR-Messino Cancer Centers in Ashville, NC; Sidney Kimmel Cancer Center in Baltimore, MD; The Ohio State University in Columbus, OH; and Yale University School of Medicine, New Haven, CT.

The study was supported by the National Cancer Institute of the National Institutes of Health under the Award Number UG1CA189823 (Alliance for Clinical Trials in Oncology NCORP Grant); UG1CA239762, UG1CA189858, UG1CA239758, and UG1CA239769

###

References: [Alliance A222001](#) - A Randomized, Double-Blind, Placebo-Controlled Phase II Study of Oxybutynin Versus Placebo for the Treatment of Hot Flashes in Men Receiving Androgen Deprivation Therapy

[Journal of Clinical Oncology](#): Alliance A222001: Oxybutynin Versus Placebo for the Treatment of Hot Flashes in Patients Receiving Androgen-Deprivation Therapy for Prostate Cancer

The Alliance for Clinical Trials in Oncology is a national leader in advancing cancer research, uniting more than 25,000 cancer specialists at 115 main institutions and 1,400 affiliates across the U.S. and Canada. As part of the National Clinical Trials Network and a leading research base for the NCI Community Oncology Research Program, the Alliance conducts pioneering, practice-changing clinical trials that improve outcomes and reshape standards of care. Its work has led to multiple FDA approvals, influenced national guidelines, and produced hundreds of high-impact publications. More than 40,000 participants have taken part in Alliance studies, and its growing biospecimen repository now includes more than 1.5 million samples, collected over the past 30 years. Learn more at www.AllianceforClinicalTrialsinOncology.org.