

Palbociclib is safe for women with advanced breast cancer who have unique gene alteration

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Women who receive palbociclib (Ibrance) to treat their advanced breast cancer and have a gene alteration that can lead to a condition known as benign ethnic neutropenia (BEN), can safely receive the drug without

major concerns of developing infections associated with neutropenia, or low white blood cell counts, say Georgetown Lombardi Comprehensive Cancer Center researchers. African American women have a higher incidence of BEN than other races and have been underrepresented in trials testing this medicine so palbociclib's safety in this population wasn't fully known.

This clinical trial result will be presented in a poster session at the San Antonio Breast Cancer Symposium on December 11, 2019, in San Antonio, Texas.

Many clinical [trials](#) require patients to have normal white blood cell counts at enrollment. Specifically, clinical trials of palbociclib have shown that women can develop neutropenia (low neutrophil counts) while taking the drug and therefore be at increased risk of infection. Neutrophils are a type of white blood cell and they are usually one of the first types of white blood cells to reach a site of infection. The lack of infection-fighting white blood cells is often an emergency situation. A BEN diagnosis carries a very low risk of infection, yet women may be given reduced dosages of palbociclib due to lower neutrophil counts even though their infection risk is low.

The phase II PALINA trial, conducted at Georgetown Lombardi and four other centers, used advanced DNA testing at the start of the trial to determine if women had the gene alteration that leads to BEN. The women took palbociclib pills and an estrogen-lowering pill (letrozole) for a maximum of one year. They were then followed to determine if their BEN status affected their safety when taking palbociclib.

"Problematically, African American women and women of African descent have higher rates of death due to [breast cancer](#) than [white women](#) and their representation in [clinical trials](#) has been historically lacking," said Filipa Lynce, MD, a physician researcher at Georgetown

Lombardi Comprehensive Cancer Center who treats patients at MedStar Georgetown University Hospital. "It was important for us to demonstrate that African American and other women with BEN can, and should, receive the same treatment regimen, in this case palbociclib, for their breast cancer as other women."

The trial enrolled 35 women from Washington, D.C., Baltimore, Chicago and Philadelphia. This current analysis showed that of the 33 women who were tested, 58% had the gene alteration that is associated with lower neutrophil counts. None of the patients in this trial progressed to neutropenia that led to a fever, nor did any of the women discontinue their treatment due to infections. Nearly half of the women did develop a high, but not life-threatening level of neutropenia, resulting in delays in taking their medications.

"We are now more confident that [palbociclib](#) can be taken safely by African American and other women with BEN, as long as their white blood cell counts are regularly monitored," said Lynce. "Our results also point out the need to design trials that enroll women with different ancestries and reflect our patient population so that study outcomes can be applicable to as many [women](#) as possible."

Provided by Georgetown University Medical Center

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