Controlling Chemo

A new clinical trial addresses a potentially harmful side effect of drug treatment for Black women with breast cancer.

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Recently, researchers at the Indiana University (IU) School of Medicine launched a study designed to better understand and treat neuropathy. More likely to affect Black women with breast cancer who undergo chemotherapy, this damage to the nerves can cause weakness, numbness or throbbing pain in the hands and feet.

Real Health spoke with Bryan P. Schneider, MD, a professor of medicine and medical and molecular genetics and the Vera Bradley Chair of Oncology at IU's School of Medicine and the lead scientist of the investigation, about the study's objectives and possible benefits for Black women.

Briefly tell us about the goal of this clinical trial and how findings will help women in the African-American community.

The goal of this study is to personalize the best type of chemotherapy for African-American women who require therapy in the curative setting for her breast cancer. Specifically, we found that African-American women are markedly more likely to get neuropathy from the class of chemotherapy drugs called the taxanes when compared to Caucasian women. Neuropathy is an inflammation of the nerves that can result in numbness, burning or tingling in the fingertips and toes and has the potential to be irreversible. This side effect can impact a woman's quality of life and lower [the chances of] survival from her breast cancer. In this trial, we will use the genetic makeup of each patient to unravel which taxane may cause the least amount of neuropathy and result in the best quality of life while still being effective at killing cancer cells.

Please describe the design, timeline, target age group of participants and other key details about the study.

The study design includes the enrollment of 240 African-American women who are planning to receive taxane chemotherapy (either docetaxel or paclitaxel) for their breast cancer. The chemotherapy can be before or after the woman has breast cancer surgery. Each patient will receive the planned standard approved chemotherapy from her oncologist, but we will ask questions and monitor women throughout treatment and for three years after treatment finishes. The goal of these questions is to better understand neuropathy and how it impacts a woman's

quality of life. This trial will include two blood draws over the time of the study to understand the impact of her genetic makeup, for monitoring blood sugar levels (which are known to impact neuropathy) and to conduct special research to understand more about why we get neuropathy. This trial just opened in August of 2019.

How does neuropathy contribute to increased risk of mortality in African-American women with breast cancer?

Because African-American women get more neuropathy and more severe neuropathy, this often results in the need to reduce the dose of chemotherapy or to stop therapy early. It appears that getting less chemotherapy drug means that not all the cancer cells in the body are destroyed, which may result in the cancer returning and leads to a higher mortality rate from breast cancer in African-American women.

Are there any specific reasons why women of African-American ancestry develop neuropathy more often than women of European ancestry?

There is an increased risk of neuropathy with obesity and diabetes, which are both more common problems in African-American women. While these may be contributing factors, this does not account for all of the increased risk. Our research team has evidence that this is also due to differences in our genetic makeup. This clinical trial will hopefully shed some light on the reasons for this imbalance and may lead to identification of ways to treat or prevent neuropathy altogether.

How do you and your team plan to engage Black women and the African-American community in your recruitment efforts for this clinical trial?

We have collaborated with two incredible advocacy groups in the Indianapolis area, R.E.D. Alliance and Pink-4-Ever. We were fortunate to have begun a relationship with them prior to the development of this trial, so we have had an opportunity to begin to listen to and jointly address the needs of the African-American community around breast health. Importantly, in collaboration with these groups, we have developed all of the patient information related to this trial and are expanding our efforts to better understand the educational and resource needs of our patients in the area of neuropathy. In addition to our local efforts, this trial is open at sites across the United States and will have a social media campaign to spread awareness about this trial.

What would you say are some of the key reasons African-Americans are underrepresented in research of this kind?

African Americans are underrepresented in almost all cancer-specific clinical trials across the U.S. The reasons for this are multifactorial but include a distrust derived from studies where

researchers did not conduct research in an appropriate, ethical and caring way. Additionally, recruitment efforts to date have not been specific to or in collaboration with the African-American community. We are hopeful to change that trend with this trial, as this is one of the first and only trials to be conducted in the cooperative group setting (a network of researchers, physicians and health care professionals at public and private institutions nationwide who are members of the group) with enrollment completely focused on African-American patients.

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