March 29, 2021

Dear Research Participant (or name):

You are receiving this letter because you are currently participating in the research study called “EA1131: A Randomized Phase III trial of Platinum Based Chemotherapy Vs. Capecitabine in Patients with Residual Triple-Negative Breast Cancer following Neoadjuvant Chemotherapy.”

We now have initial results from this study to share with you.

**WHAT HAS HAPPENED?**

While this research study has not finished accruing participants, we now have enough information to reach a conclusion that may be important to you as a participant.

From the information we now have, we know that:

* It is unlikely that cisplatin or carboplatin is better than capecitabine for reducing the chance of breast cancer recurrence following surgery in individuals with triple-negative breast cancer.
* The participants who were treated with either cisplatin or carboplatin had more significant side effects than those participants treated with capecitabine.

Based on these results, no new participants will be enrolled in the study.

**WHAT ARE YOUR TREATMENT OPTIONS NOW?**

It is important that you discuss how these findings apply to you with your study doctor.

* Study participants currently taking capecitabine as their treatment should continue to take capecitabine according to the original plan of the study.
* Study participants currently being treated with cisplatin or carboplatin may choose to continue on the same treatment, or they can change treatment to capecitabine. Participants should discuss this decision with their cancer physician to determine the best choice for them as an appropriate medical intervention.
* Study participants who have completed their course of cisplatin or carboplatin should also discuss their options with their cancer physician.

**HOW DO YOU KNOW IF THE TREATMENT YOU TOOK BENEFITED YOU?**

It is not possible to know at this time if the treatment you took helped prevent a recurrence of your type of breast cancer regardless of which chemotherapy group (capecitabine or cisplatin or carboplatin) you were in.

**WHAT HAPPENS IF YOU CHANGE FROM CISPLATIN OR CARBOPLATIN TO CAPECITABINE?**

It is not possible to know if changing treatment to capecitabine will further help prevent a recurrence of your type of breast cancer or cause more side effects. Participants should discuss this decision with their cancer physician to determine the best choice for them.

**WHAT HAPPENS NOW?**

Your continued participation in this research is important to us. Even if you change from your current treatment to capecitabine, we still wish to follow you and learn as much as we can about the treatment of triple negative breast cancer.

* We ask that all study participants continue to submit their blood samples, complete study questionnaires, and be followed by their research study teams as had been planned. These scientific studies will help the researchers learn more about the treatment of this disease.
* Those participants who have already completed their treatment will continue to be followed as desciribe in the study’s informed consent form.

If you want to stop the medication you are receiving as part of the study, you and your doctor together will decide which treatment you may receive going forward. Choices regarding further treatment will be an individual medical decision between you and your doctor. Regardless of the treatment option that you choose, the information we collect about your progress will help us to continue to understand and treat this disease.

As in any research study, you may always decide to stop participating at any time by informing your study doctor of your wishes.

**THANK YOU.**

You have been a very important part of this study, and we thank you for participating. The results from this study are very important and will help individuals in the future who are diagnosed with triple-negative breast cancer. We greatly appreciate your participation in EA1131.

Sincerely,

Letter

Description automatically generated with medium confidence

Ingrid Mayer, MD, MSCI

EA1131 Study Chair