Clinical trial summary (S2212)

Salinas Valley HEALTH

Testing Shorter Chemo-Immunotherapy Without Anthracycline Drugs for Early-Stage Triple Negative Breast Cancer

What is the purpose of this clinical trial?

This study is for people with triple negative breast cancer. It will test treatment before surgery that combines chemotherapy with immunotherapy (called **chemo-immunotherapy**).

- **Immunotherapy** uses treatments that help the immune system fight cancer.
- **Chemotherapy** (chemo) uses different drugs to kill or slow the growth of cancer cells.

For early-stage triple negative breast cancer, chemo-immunotherapy usually uses a type of chemo drug called anthracyclines. This study will test a shorter treatment that does not use anthracycline drugs.

This trial is set up to find out:

- If the treatment using fewer drugs works just as good as the usual treatment to help get rid of the cancer and prevent it from coming back
- If the treatment using fewer drugs causes fewer side effects than the usual treatment

Why is this trial important?

Fewer chemo drugs may be needed before surgery now that today's treatments are usually combined with immunotherapy. There is evidence from previous research that chemo-immunotherapy without anthracyclines may be equally good at getting rid of triple negative breast cancer.

Doctors expect that using fewer drugs for a shorter time will lessen the side effects that patients have. This trial is a chance to find out for sure if the shorter treatment can be used instead of the usual treatment.

Who can be in this trial?

This trial is for adults, age 18 or older with breast cancer that is early stage (the cancer has not spread beyond the breast or lymph nodes).

This trial is for people who:

- Have triple negative breast cancer

This trial is not for people who:

- Have breast cancer that is ER-positive, PR-positive, or HER2-positive
- Have inflammatory breast cancer
- Already had chemotherapy or radiation treatment for breast cancer
- Already had treatment with pembrolizumab or a similar immunotherapy drug
- Are pregnant

Talk with your doctor to learn more about who can join this study.

What treatments will I get?

A computer will randomly assign you to one of 2 study groups.

Group 1: Usual treatment

- **4** chemo drugs:
  - Paclitaxel
  - Carboplatin
  - Doxorubicin
  - Cyclophosphamide
- **1** immunotherapy drug:
  - Pembrolizumab
- Treatment lasts up to **8** cycles (24 weeks)

Group 2: Treatment without anthracycline drugs

- **2** chemo drugs:
  - Docetaxel
  - Carboplatin
- **1** immunotherapy drug:
  - Pembrolizumab
- Treatment lasts up to **6** cycles (18 weeks)

Your doctor will not have control over which group you are assigned to. This helps make sure the study results are fair and reliable.

How long will I be in the trial?

You will be in the study for 5 years. After you finish chemo-immunotherapy, your cancer care will continue with surgery and any other treatment that is usually recommended. You will see your study doctor at least every 6 months for follow-up study visits until 5 years after you started the study.

Are there costs? Will I get paid?

Chemo-immunotherapy drugs are not provided free in this study. Check with your health care provider and insurance provider to find out what costs will and won't be covered in this study. You will not be paid for joining the study.

Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to **www.ClinicalTrials.gov** and search using the national clinical trial number: **NCT05929768**
- For a list of trial locations, visit **swog.org/NCI-S2212**

Key information

This trial is for adults 18 years or older being

Full trial title: Shorter Anthracycline-Free Chemo Immunotherapy Adapted to Pathological Response in Early Triple Negative Breast Cancer (SCARLET), A Randomized Phase III Study

Protocol number: S2212

NCT number: NCT05929768

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Thank you! When you join a clinical trial, you're moving cancer medicine and patient care forward.