



STOP-HER2

TRIAL TITLE

The STOP-HER2 Trial:
a Phase 2 Study of **Stopping Trastuzumab - Outcomes in Patients with HER2+ Metastatic Breast Cancer**

TRIAL STATUS

Recruiting

TRIAL NUMBER

[NCT05721248](https://clinicaltrials.gov/study/NCT05721248)

TRIAL PHASE

Phase 2

PARTICIPANTS IN THE STUDY*

- Adults aged 18 and older diagnosed with HER2-positive metastatic breast cancer. Participants may be estrogen receptor-positive or negative.
- Participants must currently be receiving their first anti-HER2 therapy for metastatic HER2-positive breast cancer, which may be trastuzumab (Herceptin) with or without pertuzumab (Perjeta). Participants must have been taking this therapy for at least 3 years without evidence of the cancer getting worse.
- Participants who have had brain metastasis are eligible if they meet certain criteria.
- Participants must not be receiving any investigational medicines to treat breast cancer.

*Additional eligibility criteria may apply

BREAST CANCER
breakthroughs

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Breast Cancer Breakthroughs FACT SHEET

TRIAL DETAILS:

- Approximately 82 participants will be split into 2 groups:
 - Group one will continue their anti-HER2 therapy
 - Group two will stop their anti-HER2 therapy
- Participants will have a scan 30 days before starting the study. Once the study begins, they will be evaluated after 4-6 weeks, 12 weeks, and every 12 weeks through the end of the study.
- Each evaluation will consist of a physical exam and blood draw, and participants will have a restaging scan every 12 weeks.
- Participants in group two who show no evidence of cancer progression after one year may discontinue their anti-HER2 therapy indefinitely, although continued monitoring with imaging every 3-6 months is recommended.
- Participants in group two who experience cancer progression are strongly encouraged to resume their anti-HER2 therapy.
- Participants will be followed for 10 years.
- Researchers will measure the percentage of participants that remain progression free in each group.
- Researchers will also measure circulating tumor DNA in the participants' blood samples to determine if the presence of circulating tumor DNA can help predict the patients who can safely stop their anti-HER2 therapy.

ABOUT ANTI-HER2 THERAPY FOR METASTATIC HER2-POSITIVE BREAST CANCER:

- The standard of care for initial treatment of metastatic HER2-positive breast cancer is 4-8 cycles of a taxane, trastuzumab and pertuzumab. Patients then receive maintenance therapy of trastuzumab and pertuzumab for as long as the treatment continues to work.
- About 20% of people taking trastuzumab + pertuzumab maintenance therapy have been found to be exceptional responders and have no signs of disease progression after 5 years.
- Research is needed to better personalize the standard of care to determine who can safely stop their anti-HER2 therapy without their cancer progressing.

REFERENCES:

1. Heather Parsons, MD, Dana-Farber Cancer Institute. The STOP-HER2 Trial: a Phase 2 Study of Stopping Trastuzumab - Outcomes in Patients with HER2+ Metastatic Breast Cancer. ClinicalTrials.gov identifier: NCT05721248. Updated October 1, 2024. Accessed October 25, 2024. <https://clinicaltrials.gov/study/NCT05721248>
2. Swain S.M. et al. Pertuzumab, Trastuzumab, and Docetaxel in Her2-Positive Metastatic Breast Cancer. New England Journal of Medicine. 2015. DOI: 10.1056/NEJMoa1413513
3. <https://www.dana-farber.org/newsroom/features/expanding-possibilities>

For more information, go to [komen.org/breakthroughs](https://www.komen.org/breakthroughs)