ForPatients
by Roche

Inflammatory Breast Cancer Locally Advanced Breast Cancer Breast Cancer HER-2 Positive Breast Cancer Early Breast Cancer HER2-Positive Breast Cancer

A study to assess whether people with early or locally advanced/ inflammatory HER2-positive breast cancer prefer to receive combined pertuzumab and trastuzumab treatment at home or in a hospital setting

A Study to Evaluate Patient Preference for Home Administration of Fixed-Dose Combination of Pertuzumab and Trastuzumab for Subcutaneous Administration in Participants With Early or Locally Advanced/Inflammatory HER2-Positive Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	18 Countries	NCT05415215 2023-506380-33-00 MO43110

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This is a Phase IIIb, multinational, multicenter, randomized, open-label study to evaluate patient preference of the fixed-dose combination of pertuzumab and trastuzumab for subcutaneous use (PH FDC SC) administration in the home setting compared with the hospital setting during the cross-over period of adjuvant treatment in participants with early or locally advanced/inflammatory human epidermal growth factor receptor 2-positive (HER2+) breast cancer.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT05415215 2023-506380-33-00 MO43110
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is this study needed?

HER2, also known as human epidermal growth factor receptor 2, is a protein involved in normal cell growth. It can be made in larger than normal amounts by some types of cancer cells, including breast cancer, and cause cancer cells to grow more quickly. The standard treatment for HER2-positive breast cancer that has not spread in the body or has only spread to nearby tissues is a combination of medicines. These medicines are called pertuzumab and trastuzumab. They are given with chemotherapy. Previous studies show that pertuzumab and trastuzumab treatment works equally well when given as a drip into a vein (which takes a few hours), or when given as an injection under the skin (which takes a few minutes). This study will look at whether people with HER2-positive breast cancer prefer this treatment as injections under the skin at home, or in a hospital.

2. Who can take part in the study?

People (males and females) of 18 years of age or older with HER2-positive breast cancer, that has not spread in the body or has only spread to nearby tissues, can take part in the study if they plan to have surgery to remove their tumour and are able to have injections under the skin of their thigh.

People may not be able to take part in this study if they have breast cancer that has spread to other parts of the body. People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

Participants may have to be a part of this study for about 1 and a half to 2 years. Participants will be screened to check if they are able to participate in the study. The screening period will take place from 1 day to 1 month before the start of treatment. Treatment will be given in 2 parts:

Part 1 (before surgery)

Everyone who joins this study will join 1 of 2 groups at random (like flipping a coin) and be given chemotherapy in the hospital AND either:

- **Group A:** pertuzumab and trastuzumab, given as a drip into a vein every 3 weeks
- **Group B:** OR pertuzumab and trastuzumab, given as an injection under the skin every 3 weeks

Participants will have a 1 in 3 chance of being in Group A, and a 2 in 3 chance of being in Group B. This is an open-label study, which means everyone involved including the participant and the study doctor, will know the study treatment the participant has been given. Participants will then have surgery to remove the cancer within 6 weeks of their last dose of pertuzumab and trastuzumab with chemotherapy.

Part 2 (from 2 weeks after surgery)

Participants from Part 1 with remaining cancer cells in tissues removed by surgery will be given trastuzumab emtansine as a drip into a vein every 3 weeks in the hospital. They may also be given radiotherapy.

Participants from Part 1 who have no cancer remaining in tissues removed by surgery will be given pertuzumab and trastuzumab as an injection under the skin every 3 weeks for 2 treatment cycles in the hospital. They may also be given radiotherapy. This will happen during the 'run-in' period. Participants will then join 1 of 2 groups randomly (like flipping a coin) and be given pertuzumab and trastuzumab as an injection under the skin every 3 weeks during the 'cross-over' period. This will be either:

- In the hospital for 2 months, then in their home for 2 months
- OR, in their home for 2 months, then in the hospital for 2 months

Participants will have an equal chance of being placed in either group.

Participants can then choose to receive pertuzumab and trastuzumab at home or in the hospital, given as an injection under the skin every 3 weeks. This is called the 'treatment continuation' period. All treatments will be given by a nurse or a doctor.

During this study, the study doctor will see participants every 3 weeks. Some visits will take place in the participant's home by a nurse. The doctor or nurse will see how well the treatment is working and any unwanted effects participants may have. Participants will have a follow-up visit after 6 to 9 months of completing study treatment, during which the study doctor will check on the participant's wellbeing. Total time of participation in the study will be about 1 and a half to 2 years. Participants have the right to stop study treatment and leave the study at any time if they wish to do so. Participants will not lose access to regular care if they stop study treatment.

4. What are the main results measured in this study?

The main result measured in the study is the number of participants who prefer treatment at home rather than in the hospital, based on the responses provided in a Patient Preference Questionnaire.

Other key results measured in the study include:

- The number of healthcare professionals who find it more convenient and faster to give treatment as an injection under the skin than as a drip into a vein
- The number of participants who have no cancer following treatment in Part 1 and surgery
- Changes in how participants' health impacts their daily life and their ability to function and enjoy life
- The number of participants who ask for treatment at home rather than in the hospital during the treatment continuation period

- The number, type and seriousness of unwanted effects that participants experience

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study medicines

Participants may have unwanted effects of the medicines used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Pertuzumab, trastuzumab and trastuzumab emtansine

Participants will be told about the known unwanted effects of pertuzumab, trastuzumab and trastuzumab emtansine, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects of pertuzumab and trastuzumab include frequent, watery stools, feeling or being sick, hair loss, feeling tired or weak, difficulty pooing, and fever. Known unwanted effects of trastuzumab emtansine include difficulty breathing, feeling tired or weak, feeling or being sick and fever.

Pertuzumab and trastuzumab will be given as a drip into a vein or an injection under the skin. Trastuzumab emtansine will be given as a drip into a vein. Known unwanted effects of drips into a vein and injections under the skin include feeling or being sick, a feeling of coldness that makes the body shiver, low or high blood pressure, fever, reddening of the skin, pain or discomfort in the head, a rapid heart rate or heart beats out of rhythm, frequent, watery stools, shortness of breath, cough and throat irritation or swelling. The study medicine(s) may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.