



A guide to your appointments

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An introduction to this appointment guide

What is the HER2CLIMB-05 Clinical Research Study?

The HER2CLIMB-05 Clinical Research Study is looking to explore how well an investigational study drug works as a maintenance therapy, alongside receiving standard of care, for people living with unresectable locally advanced or metastatic HER2-positive breast cancer who have received their first treatment with trastuzumab and pertuzumab.

Information about HER2-positive breast cancer, the investigational study drug and the clinical research study is available in the previous brochure provided to you.





What is included in this guide?

When taking part in a clinical research study, it's normal to have lots of questions about what will be involved and what you will need to do.

Throughout the clinical research study, tests and procedures will take place to find out how well the investigational study drug works at helping to stop the cancer from getting worse, and if it improves the quality of life for those taking part.

This guide describes the tests and procedures that are involved and explains what will happen at each of your scheduled appointments.

Remember, if you're unsure on any of the procedures involved or would like more information, your study team will be available to answer any questions or help you with any concerns that you may have.

If you're unable to attend any of the appointments, please let the study team know as soon as possible.

Understanding the tests and procedures

Before we explain what happens at each of your scheduled appointments, let's first take a look at some of the main tests and procedures involved, so you will know what to expect.



Tests and procedures



Medical history

This involves answering some questions about yourself and your health. It also involves you giving information on any previous breast cancer treatments that you have had.



Physical exam

This includes measuring your blood pressure (by placing a cuff around your arm), heart rate (by using a monitor that is placed on your finger), temperature, height, and weight.



Pregnancy test

If you can become pregnant, we will take either a blood or urine sample for a pregnancy test.



Body and brain scans

Your doctor will order tests like a magnetic resonance imaging (MRI), computed tomography (CT), or positron emission tomography (PET) scan to take images and look for signs of cancer throughout your body, including your brain.



Blood samples

Blood samples will be taken 1 or 2 times during each cycle for safety and research tests. Depending on the type of test, the total amount taken during one appointment will be between about 1 and 5 teaspoons, but we will only need to insert 1 needle to take the sample. Your body will make new blood to replace the blood that we take for these tests. Your blood samples will be tested to check on your disease and for other research reasons — these reasons will be explained fully to you in the informed consent form.





Tumor sample

We can either use an old sample, if you have one, or we can take a new sample. If we take a new sample, this will include inserting a needle into your body and taking a small piece of the tumor. We will give you medicine to numb the area before we take the sample.



Bone scan

We may do a bone scan to look for signs of cancer in your bones. Before the scan, we will inject a type of dye into your vein that is used to make certain parts of your body more visible on the scan images. A very small amount is used, and most people experience no serious unwanted effects. You will then lie down while the scanner takes the images. This will either be an MRI, CT, or PET scan, and you will have the same type of bone scan throughout the study.



Electrocardiogram (ECG)

This is a painless test that measures the electrical activity and health of your heart. It involves attaching sensors to the skin, which are used to detect the electrical signals produced by your heart each time it beats.



Side effects review

A side effect is anything a drug does to your body that is not part of how the drug treats disease. You will be closely monitored for any side effects that you are experiencing, which may or may not be related to the study drug.



Medication review

This will include a review of medications used for your cancer and any other therapy you are using now or have used in the past.





Questionnaires

During some appointments, you will be asked to answer some questions related to your physical, mental, and social health. These questionnaires will be electronic (such as on tablet that will be provided by the study team).



ECHO or MUGA

You will have one of two scans that produce pictures of your heart to measure how well your heart is working. If you have an ECHO test, this might involve giving you medicine into a vein in your arm (known as intravenous, “IV”). If you have a MUGA, we will give you liquid through an IV. This liquid contains radiation, which will help us to take pictures of your heart.



Administration of the study drug

In addition to taking the investigational study drug as a tablet, twice a day, you will receive the other study drugs into a vein in your arm (IV), an injection under your skin, or both. Your study doctor will let you know more about which type you will get.

What will happen at your appointments?













Screening period

Before you begin to receive the investigational study drug, you will first take part in the screening/baseline appointment to confirm that you are able to take part. You will also sign the informed consent form. Following screening, you will enter the treatment period to receive the study drugs.

Screening/baseline appointment

During screening, you will take part in some tests and procedures to confirm if you are able to join the HER2CLIMB-05 Clinical Research Study. These tests will be done at 1 or 2 appointments, during the month before the first study appointments.

Tests and procedures will include:

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|  Medical history |  ECG |
|  Tumor sample |  Body and brain scans |
|  Physical examination |  Bone scan (if bone cancer is known or suspected) |
|  Pregnancy test |  Side effects review |
|  Blood samples |  Medication review |
|  ECHO or MUGA (if you have not already had one of these within the 4 weeks leading up to your first study treatment) |  Questionnaires |

After screening, if you can be in the study and choose to take part, you will be randomly assigned (like flipping a coin) to receive the investigational study drug or a placebo, alongside receiving standard of care (trastuzumab and pertuzumab).



Treatment period








Throughout the treatment period, the study drugs will be given in 21-day cycles. This means:

- You will be given trastuzumab and pertuzumab on the first day of every cycle.
- You will also take tablets (the placebo or investigational study drug) twice daily.




The tablets are round- or oval-shaped, and you will receive a “dosing guide,” which provides more information about these tablets, such as when and how to take them.

The number of cycles will vary depending on your response to the study drug. If your cancer is stable or gets better, you may keep getting the study drugs until the study closes.




Day 1 of every 21-day cycle

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|--|---|
|  Physical examination |  Pregnancy test |
|  Blood samples |  Side effects review |
|  Medication review |  Questionnaires |
|  Administration of the study drug | |
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Day 12 of cycles 1 and 2 only

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|  Blood samples |  Side effects review |
|  Medication review | |
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Every 9 weeks, starting at day 1 of cycle 1

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|  Side effects review |  Medication review |
|  Body and brain* scans | |

**You will have a brain scan (MRI) every 9 weeks if you do have signs of cancer in your brain or you have a history of cancer in your brain. If you do not have signs of cancer in your brain or a history of cancer in your brain, you will have a brain scan every 27 weeks.*

Every 27 weeks, starting at day 1 of cycle 1



Blood samples



Body and brain scans



Bone scan (if bone cancer is known or suspected)



Side effects review



Medication review

Every 12 weeks



Blood samples



ECHO or MUGA



Side effects review



Medication review







End of treatment/ follow-up period

After your regular study appointments are over, you will be asked to come into the clinic for the end of treatment appointment, where the study team will check how you are and complete some more tests. Following this appointment, you will enter the follow-up period, where appointments take place every 12 weeks.






End of treatment appointment

The end of treatment appointment will be 30-37 days after your last dose of study medication. Tests and procedures during this appointment will include:

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|  Physical examination |  Blood samples |
|  ECHO or MUGA |  Body and brain scans |
|  Bone scan (if bone cancer is known or suspected) |  Side effects review |
|  Medication review |  Questionnaires |

Follow-up appointments

Follow-up appointments will happen every 12 weeks. Tests and procedures during these appointments may include:

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|--|--|
|  Bone scan (if bone cancer is known or suspected) |  Body and brain scans |
|  Medication review |  Side effects review |
|  Questionnaires | |

While follow-up appointments occur every 12 weeks, please note that you will have body, brain and bone scans at the same frequency you did during the treatment period (e.g., every 9 weeks or every 27 weeks), unless your cancer gets worse.

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Please do not hesitate to ask questions or raise any concerns with your study doctor — they are there to help.

Study team contact information:

Name:

Telephone:

Email:



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