ForPatients
by Roche

Breast Cancer HER-2 Positive HER2-positive Early Breast Cancer

A Clinical Trial to Assess Preference and Satisfaction with Pertuzumab plus Trastuzumab Given into a Vein ('Intravenous') or Given by an Injection Under the Skin ('Subcutaneous') in Patients with HER2-Positive Early Breast Cancer (MO40628)

A Study to Evaluate Patient Preference and Satisfaction of Subcutaneous Administration of the Fixed-Dose Combination of Pertuzumab and Trastuzumab in Participants With HER2-Positive Early Breast Cancer (MO40628)

Trial Status	Trial Runs In	Trial Identifier
Completed	18 Countries	NCT03674112 2018-002153-30 MO40628

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 II, randomized, multicentre, multinational, open-label, cross-over study in adult patients who have completed neoadjuvant chemotherapy with neoadjuvant pertuzumab and trastuzumab and have undergone surgical treatment of human epidermal growth factor receptor 2 (HER2)-positive early breast cancer. The study will consist of two adjuvant treatment periods: a treatment cross-over period and a treatment continuation period. It will evaluate participant-reported preference for a subcutaneously administered fixed-dose combination formulation (FDC SC) of pertuzumab and trastuzumab compared with intravenously (IV) administered pertuzumab and trastuzumab formulations. The study will also evaluate participant-reported satisfaction with pertuzumab and trastuzumab FDC SC and health-related quality of life outcomes; healthcare professionals' perceptions of time/resource use and convenience of pertuzumab and trastuzumab FDC SC compared with pertuzumab and trastuzumab IV formulations; as well as the safety and efficacy of each study regimen.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT03674112 2018-002153-30 MO40628
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	**>= 18 Years**	**No**

What is the purpose of the MO40628 clinical trial? This clinical trial is recruiting people who have breast cancer at an early stage (breast cancer that has not spread to anywhere else in the body). It is for people whose breast cancer is described as ‘HER2’ positive (or HER2+). This means the breast cancer cells have tested positive for a protein called HER2.

The aim of the clinical trial is to understand whether people prefer to be given the treatment for their breast cancer as a drug into the vein (this is called an ‘intravenous infusion’) or as an injection under the skin (also known as a ‘subcutaneous injection’).

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must have previously been given treatment with pertuzumab, trastuzumab and chemotherapy for your cancer no more than 9 weeks ago. You must also have had surgery to remove your breast tissue after your previous treatment.

If you would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor who will give you all the information you need to make your decision about taking part in the clinical trial. You will find the clinical trial locations at the top of this page.

You will have some blood tests to make sure that you are able to receive the treatments given in this clinical trial. Some of these tests may be part of your regular medical care and may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial and what other treatments are available so that you may decide if you still want to take part.

If you agree to take part in this clinical trial, your doctor will need to confirm once more that you have the right tumour being investigated in this clinical trial, and then you may be able to be given treatment for your specific type of cancer.

What treatment will I be given if I join this clinical trial? At first, everyone who joins the clinical trial will be put into one of two groups randomly (like flipping a coin). Both groups of patients will get pertuzumab and trastuzumab, once every 3 weeks, but one group will get the drugs into a vein (this ‘intravenous’ method is what you would currently receive if you do not take part in the trial) and the other group by an injection under the skin (‘subcutaneous’).

After you have been given the first treatment 3 times, you will switch over to be given the same drugs but by the other method.

How often will I be seen in follow-up appointments, and for how long? Once you have been given pertuzumab and trastuzumab 6 times you will be asked to complete questionnaires to help doctors understand which was your preferred way of being given the drugs. If you did not have side effects or your side effects were mild with your preferred method, you will be able to continue taking that treatment until you have been given 18 rounds of treatment in total.

You are free to stop this treatment at any time. After you have been given your last dose of treatment, you will need to meet your doctor after 28 days for a check-up. You will then need to meet your doctor several times a year, for up to 3 years, to discuss how well your cancer is under control after stopping the treatment. This is normal procedure after receiving treatment for breast cancer, and it also gives you the opportunity to discuss any side effects that you may be having with your doctor.

What happens if I'm unable to take part in this clinical trial? If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other treatments for you that you can be given or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care by asking your doctor if you can take part in this trial.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT03674112