ForPatients
by Roche

Breast Cancer HER-2 PositiveHER2-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 information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Randomized, Multicenter, Open-Label Cross-Over Study to Evaluate Patient Preference and Satisfaction of Subcutaneous Administration of the Fixed-Dose Combination of Pertuzumab and Trastuzumab in Patients With HER2-Positive Early Breast Cancer

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	Phase 2
Sponsor	Phase

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NCT03674112 2018-002153-30 MO40628
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

Disease-specific criteria:

- Female or male with histologically confirmed, HER2-positive (HER2+) inflammatory, locally advanced or early-stage breast cancer who have received neoadjuvant pertuzumab and trastuzumab and have completed neoadjuvant chemotherapy and subsequently undergone surgery for their breast cancer.
- HER2+ breast cancer assessed at the local laboratory prior to initiation of neoadjuvant therapy. HER2+ status must be determined based on breast biopsy material obtained prior to neoadjuvant treatment and is defined as 3+ by immunohistochemistry (IHC) and/or positive by HER2 amplification

by in situ hybridization (ISH) with a ratio of #2 for the number of HER2 gene copies to the number of chromosome 17 copies.
- Hormone receptor status of the primary tumour determined by local assessment. Hormone receptor status may be either positive or negative.
- Completed all neoadjuvant chemotherapy and surgery. Adjuvant radiotherapy may be planned or ongoing at study entry and adjuvant hormone therapy is allowed during the study. Note that study treatment cannot be initiated within <2 weeks of surgery but must be initiated #9 weeks from the last administration of systemic neoadjuvant therapy.
- No evidence of residual, locally recurrent or metastatic disease after completion of surgery. Patients with clinical suspicion of metastases must undergo radiological assessments per institutional practice to rule out distant disease.
- Wound healing after breast cancer surgery adequate per investigator's assessment to allow initiation of study treatment within #9 weeks of last systemic neoadjuvant therapy
- No adjuvant chemotherapy planned. Note that adjuvant hormonal treatment is allowed during the study.

General criteria:

- Ability to comply with the study protocol, in the investigator's judgment
- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- Intact skin at planned site of subcutaneous injections (thigh)
- Left ventricular ejection fraction (LVEF) #55% measured by echocardiogram (ECHO) or multiple-gated acquisition (MUGA) scan within 28 days of study randomization
- No major surgical procedure unrelated to breast cancer within 28 days prior to randomization or anticipation of the need for major surgery during the course of study treatment
- For women of childbearing potential: agreement to remain abstinent or use contraceptive measures, and agreement to refrain from donating eggs, Women must remain abstinent or use non-hormonal contraceptive methods with a failure rate of <1% per year, or two effective non-hormonal contraceptive methods during the study treatment periods and for 7 months after the last dose of study treatment
- For men: agreement to remain abstinent or use a condom, and agreement to refrain from donating sperm, men must remain abstinent or use a condom during the study treatment periods and for seven months after the last dose of study treatment to avoid exposing the embryo. Men must refrain from donating sperm during this same period
- A negative serum pregnancy test must be available prior to randomization for women of childbearing potential

Exclusion Criteria:

Cancer-specific criteria:

- Stage IV (metastatic) breast cancer
- Current or prior history of active malignancy within the last five years. Appropriately treated non-melanoma skin cancer; in situ carcinomas, including cervix, colon, or skin; or Stage I uterine cancer within the last five years are allowed
- Previous systemic therapy for treatment or prevention of breast cancer, except neoadjuvant Perjeta, Herceptin and chemotherapy for current breast cancer

General criteria:

- Investigational treatment within four weeks of enrolment
- Serious cardiac illness or medical conditions

- History of ventricular dysrhythmias or risk factors for ventricular dysrhythmias, such as structural heart disease, coronary heart disease, clinically significant electrolyte abnormalities, or family history of sudden unexplained death or long QT syndrome
- Inadequate bone marrow, renal and impaired liver function
- Current severe, uncontrolled systemic disease that may interfere with planned treatment
- Pregnant or breastfeeding, or intending to become pregnant during the study or within seven months after the last dose of study treatment. Women of childbearing potential must have a negative serum pregnancy test result within seven days prior to initiation of study treatment
- Any serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in, and completion of, the study
- Known active liver disease, for example, active viral hepatitis infection, autoimmune hepatic disorders, or sclerosing cholangitis
- Concurrent, serious, uncontrolled infections, or known infection with human immunodeficiency virus (HIV)
- Known hypersensitivity to any of the study drugs, excipients, and/or murine proteins
- Current chronic daily treatment with corticosteroids