KURZPROTOKOLL
FeDeriCa_WO40324

Öffentlicher Titel	Phase III Studie zu Pertuzumab und Trastuzumab bei HER2-positivem Brustkrebs
Wissenschaftl. Titel	A phase III, randomized, multicenter, open-label, two-arm study to evaluate the pharmacokinetics, efficacy, and safety of subcutaneous administration of the fixed-dose combination of pertuzumab and trastuzumab in combination with chemotherapy in patients with HER2-positive early breast cancer.
Kurztitel	FeDeriCa_WO40324
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: Erstlinie Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher

Einschlusskriterien

- Ability to comply with the study protocol, in the investigator's judgment
- Female and male patients with Stage II - IIIC (T2-T4, N0-N3, M0), locally advanced, inflammatory, or early-stage, unilateral, and histologically confirmed invasive breast cancer
- Primary tumor >2 cm in diameter, or node-positive
- HER2-positive breast cancer confirmed by a central laboratory prior to study enrollment. HER2-positive status will be determined based on pretreatment breast biopsy material.
- Hormone receptor status of the primary tumor, centrally confirmed
- Patient agreement to undergo mastectomy or breast conserving surgery after neoadjuvant therapy
- Availability of formalin-fixed, paraffin-embedded tumor tissue block for central confirmation of HER2 and hormone receptor status and additional biomarker research
- Baseline left ventricular ejection fraction (LVEF) greater than or equal to (>/=) 55% measured by echocardiogram or multiple-gated acquisition scan
- For women of childbearing potential (WOCBP) who are sexually active: agreement to remain abstinent or use one highly effective non-hormonal contraceptive method with a failure rate of < 1% per year, or two effective non-hormonal contraceptive methods during the treatment period and for 7 months after the last dose of HER2-targeted therapy
- For men: men must remain abstinent or use a condom with a spermicidal product during the treatment period and for 7 months after the last dose of HER2-targeted therapy 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 WOCBP, unless they have undergone surgical sterilization
- 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

Ausschlusskriterien

- Stage IV (metastatic) breast cancer
- Patients with a history of invasive breast cancer
- Patients with a history of concurrent or previously treated non-breast malignancies except for appropriately treated 1) non-melanoma skin cancer and/or 2) in situ carcinomas, including cervix, colon, and skin
- Patients who have received any previous systemic therapy for treatment or prevention of breast cancer, or radiation therapy for treatment of cancer

	- Patients who have a past history of ductal carcinoma in situ or lobular carcinoma in situ if they have received any systemic therapy for its treatment or radiation therapy to the ipsilateral breast - Patients with high-risk for breast cancer who have received chemo-preventative drugs in the past - Patients with multicentric breast cancer, unless all tumors are HER2-positive - Patients with bilateral breast cancer - Patients who have undergone an excisional biopsy of primary tumor and/or axillary lymph nodes - Axillary lymph node dissection prior to initiation of neoadjuvant therapy - Sentinel lymph node biopsy prior to neoadjuvant therapy - Treatment with any investigational drug within 28 days prior to randomization - Serious cardiac illness or medical conditions - Inadequate bone marrow function, renal function or 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 7 months after the last dose of HER2-targeted therapy - 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 HIV - Known hypersensitivity to study drugs, excipients, and/or murine proteins - Current chronic daily treatment with corticosteroids - History of other malignancy within 5 years prior to screening, except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, or Stage I uterine cancer - 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
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu pos.
Sponsor	Roche Pharma AG
Registrierung in anderen Studienregistern	EudraCT 2017-004897-32 ClinicalTrials.gov NCT03493854