# Clinical Trials Data ERBB2 - Document 42

# Neoadjuvant 5-fluorouracil, Epirubicin and Cyclophosphamide (FEC) Followed by Weekly Paclitaxel and Trastuzumab in Her2 Positive Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01340430

"eligibilityCriteria": "Inclusion Criteria\n\n1. Performance StatusEstearn Cooperative Oncology Group (ECOG) 0-1\n2. Histologically confirmed invasive breast cancer,\n3. Primary tumour greater \u2265 2 cm diameter, measured by clinical examination and mammography or echography or Nuclear Magnetic Resonance (NMR) candidate to neoadjuvant chemotherapy ,\n4. Any N,\n5. No evidence of metastasis (M0);\n6. Over expression and/or amplification of HER2 in the invasive component of the primary tumour according to one of the following definitions:\n7. 3+ over expression by immunohistochemistry (IHC) (\\> 30% of invasive tumour cells),\n8. 2+ or 3+ (in 30% o less neoplastic cells) overexpression by IHC and in situ hybridization (FISH/CISH) test demonstrating Her2 gene amplication ,\n9. Her 2 gene amplication by FISH/CISH (ratio \\> 2.2);\n10. Known hormone receptor status\n11. Hematopoietic status:\n\n 1. absolute neutrophil count \u2265 1.5 x 109/L,\n 2. platelet count \u2265 100 x 109/L,\n12. Hepatic status:\n\n 1. serum total bilirubin \u2264 1.5 x ULN. In the case of known Gilbert's syndrome a higher serum total bilirubin (\\< 2 x ULN) is allowed,\n 2. aspartate aminotransferase (AST) and alanine aminotransferase (ALT) \u2264 2.5 times ULN,\n 3. alkaline phosphatase \u2264 2.5 times ULN;\n13. Renal status:\n\n a. Creatinine \u2264 2.0 mg/dL;\n14. Cardiovascular:\n\n a. baseline left ventricular ejection fraction (LVEF) \u2265 50% measured by echocardiography or multigate acquisition scan (MUGA);\n15. For women of childbearing potential negative serum pregnancy test\n16. Written informed consent.\n\nExclusion Criteria:\n\n1. Male gender\n2. Pregnant or lactating women\n3. Received any prior treatment for primary invasive breast cancer\n4. Known history of uncontrolled or symptomatic angina, clinically significant arrhythmias, congestive heart failure, transmural myocardial infarction, uncontrolled hypertension (\\> 180/110), unstable diabetes mellitus, dyspnoea at rest or chronic therapy with oxygen;\n5. Active or uncontrolled infection,\n6. Dementia altered mental status or any psychiatric condition that would prevent the under standing or rendering of informed consent,\n7. Concurrent neoadjuvant cancer therapy (chemotherapy, radiation therapy, immunotherapy, biologic therapy other than the trial therapies),\n8. Previous or concomitant malignancy within the past 3 years EXCEPT adequately treated basal or squamous cell carcinoma of the skin or in situ carcinoma of the cervix.\n9. Concurrent disease or condition that would have make the subject inappropriate for study participation or any serious medical disorder that would interfere with the subject's safety.",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a ERBB2 gene mutation be eligible for the clinical trial?

Answer:  
Based on the inclusion criteria provided in the clinical trial information, a patient with an ERBB2 gene mutation, commonly referred to as HER2 (human epidermal growth factor receptor 2) overexpression or amplification, would be eligible for the trial. The eligibility criteria specifically mention the need for overexpression and/or amplification of HER2 in the invasive component of the primary tumor, which can be confirmed through immunohistochemistry (IHC) or in situ hybridization methods like FISH or CISH.  
  
If the patient's tumor shows HER2 (ERBB2) overexpression or amplification according to these criteria, they would meet this requirement of the trial. However, eligibility also depends on meeting all other criteria, including factors related to the patient's health, breast cancer characteristics, and lab test results.