# 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:  
The eligibility criteria mention "Over expression and/or amplification of HER2". ERBB2 is the gene that encodes the HER2 protein. Therefore, a patient with an ERBB2 gene mutation, which likely leads to overexpression or amplification of the HER2 protein, \*could\* be eligible.  
  
However, simply having the mutation isn't enough. The patient must also fulfill \*all\* other inclusion criteria (e.g., female, specific tumor size, no metastases, acceptable bloodwork, etc.) and \*none\* of the exclusion criteria (e.g., no prior breast cancer treatment, no active infections, etc.). The trial specifically requires confirmation of HER2 overexpression/amplification via IHC or FISH/CISH testing. So, the presence of the ERBB2 mutation itself doesn't guarantee eligibility; appropriate testing and meeting all other criteria are essential.