# Clinical Trials Data ERBB2 - Document 21

# Pre Operative Trastuzumab in Operable Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01785420

"eligibilityCriteria": "Inclusion Criteria:a.\n\n1. Female subjects aged 18 years or older.\n2. Histologically and/or cytologically confirmed diagnosis of breast cancer. Clinical stages breast cancer: HER2 positive, T1 or T2 or T3, N0 or N1, resectable T4, or resectable N2, (all M0)\n3. Documentation of erbB-2 gene amplification by FISH (as defined by a ratio \\>2.2) or chromogenic in situ hybridization (CISH, as defined by the manufacturer's kit instruction) or documentation of erbB-2-overexpression by IHC (defined as IHC3+, or IHC2+ with FISH or CISH confirmation) based on local laboratory.\n4. LVEF within institutional range of normal as measured by MUGA or ECHO.\n5. Screening laboratory values within the following parameters:\n\n 1. Absolute neutrophil count (ANC) \u22651.5 x 109 /L (1500/mm3)\n 2. Platelet count \u2265100 x 109/L (100,000/mm3)\n 3. Hemoglobin \u22659.0 g/dL (90 g/L)\n 4. Serum creatinine \u22641.5 x upper limit of normal (ULN)\n 5. Total bilirubin \u22641.5 x ULN (\\<3 ULN if Gilbert's disease) 6Aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT)\n\n \* 2.5 x ULN\n\nExclusion Criteria:\n\n1. Bilateral breast cancer\n2. Active uncontrolled cardiac disease, including cardiomyopathy, CHF (New York Heart Association \\[NYHA\\] functional classification of \u22653), unstable angina, and myocardial infarction (within 12 months of study entry).\n3. Inadequately controlled hypertension (ie, systolic blood pressure \\[BP\\] \\> 180 mm Hg or diastolic BP \\> 100 mm Hg).\n4. Family history of congenital long or short QT syndrome, Brugada syndrome or QT/QTc interval \\> 0.45 second or known history of QT/QTc prolongation or torsade de pointe (TdP).\n5. Significant chronic gastrointestinal disorder with diarrhea as a major symptom (eg, Crohn's disease, malabsorption, or grade \u22652 diarrhea of any etiology at baseline).\n6. Women who are pregnant, breast-feeding.",  
 "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 for this clinical trial, a female patient with a mutation in the ERBB2 (also known as HER2 or erbB-2) gene would likely be eligible, as long as she meets the other criteria. The trial requires documentation of HER2 positivity in breast cancer, which can be demonstrated by:  
  
1. HER2 gene amplification by FISH (Fluorescence In Situ Hybridization) with a ratio greater than 2.2.  
2. Chromogenic In Situ Hybridization (CISH) as per the manufacturer's instructions.  
3. HER2 overexpression by Immunohistochemistry (IHC) scored as IHC3+, or IHC2+ with FISH or CISH confirmation.  
  
The ERBB2 gene mutation needs to be related to HER2 positivity, which is often associated with breast cancer. If the mutation results in gene amplification or overexpression as described above, the patient would meet this specific eligibility criterion.  
  
Additionally, the patient would need to satisfy all the other inclusion criteria and not fall under any of the exclusion criteria. For instance, candidates must have an acceptable left ventricular ejection fraction (LVEF), meet specified laboratory value thresholds, and not have conditions listed under the exclusions such as uncontrolled cardiac disease or bilateral breast cancer.  
  
Ultimately, specific details about the patient's ERBB2 mutation and overall medical condition would be needed to determine complete eligibility. If the patient meets all inclusion criteria relevant to HER2 positivity and lacks any exclusion factors, she should qualify for the study.