# Clinical Trials Data ERBB2 - Document 50

# Chemotherapy for Elderly Patients Diagnosed With Localized HER2 Positive Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT02102438

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Clinical or Pathological Stage I- IIIA breast adenocarcinoma.\n\* HER2 overexpression or amplification defined by immunohistochemistry staining of +3 or positive fluorescence in situ hybridization (FISH) test.\n\* Age \u2265 65 years old.\n\* WHO performance status less than 2; adequate hematologic (granulocyte count \u2265 2 X 109/L, platelet count \u2265100 X109/L) and hepatic (transaminases \u2264 1.5 X the upper limit of normal (ULN), alkaline phosphatases \u2264 2.5 times ULN, and bilirubin \u2264 ULN) tests; and normal cardiac function (baseline left ventricular ejection fraction at least \u2265 55%)\n\nExclusion Criteria:\n\n\* Radiologic imaging of metastatic disease.\n\* History of cardiac disease contraindicating anthracyclines, uncontrolled essential hypertension or diabetes, stroke or any other comorbidity that could potentially compromise chemotherapy treatment, such as chronic obstructive pulmonary disease.\n\* Any previous treatment with anti HER2 therapy.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "65 Years",  
"stdAges": [  
"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 eligibility criteria provided for the clinical trial, a patient with an ERBB2 gene mutation may be eligible, but it depends on the nature of the mutation and how it relates to HER2 status, since ERBB2 is the gene that encodes the HER2 protein.   
  
The key inclusion criterion relevant to your question is:  
  
- The patient must have HER2 overexpression or amplification, which is defined by immunohistochemistry (IHC) staining of +3 or by a positive fluorescence in situ hybridization (FISH) test.  
  
If the ERBB2 mutation results in HER2 overexpression or HER2 amplification as described, and the patient meets all other criteria such as age (≥ 65 years old), performance status, and required hematologic, hepatic, and cardiac function, then the patient would be eligible.  
  
It's important to verify whether the specific mutation in the ERBB2 gene corresponds to HER2 overexpression or amplification as defined by the clinical trial criteria. If it does not, the patient would not be eligible based on this inclusion criterion.