# 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:  
This trial requires \*\*HER2 overexpression or amplification\*\*, as determined by specific tests (immunohistochemistry or FISH). An ERBB2 gene mutation is \*related\* to HER2, as ERBB2 is the gene that codes for the HER2 protein. \*\*However, having an ERBB2 mutation doesn't automatically mean the patient will have HER2 overexpression or amplification.\*\* These are distinct findings.  
  
Therefore, based on the information provided, \*\*we cannot determine if a patient with \*only\* an ERBB2 gene mutation would be eligible.\*\* They would need to undergo testing specifically for HER2 overexpression/amplification (IHC or FISH) to meet the eligibility criteria.