# Clinical Trials Data ERBB2 - Document 38

# Efficacy and Safety Of Xeloda as Sequential Adjuvant Therapy After Chemotherapy in Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01662128

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Karnofsky \u2265 70\n2. Provision of informed consent\n3. Pathological confirmation of breast cancer and exclusion of other metastases.\n4. Pathological confirmation of triple negative or Her-2 positive or with more than 4 axillary lymph node metastasis\n5. The patients have finished the chemotherapy of Anthracycline and/or Taxane.And it's no more than 28 days from accepting the last chemotherapy.\n6. Laboratory criteria:\n\nPLT \u2265 100\\\*109/L WBC \u2265 4000/mm3 HGB \u2265 10g/dl GOT,GPT,ALP \u2264 2\\\*ULN TBIL,DBIL,CCr \u2264 1.5\\\*ULN\n\nExclusion Criteria:\n\n1. Pregnant or lactation woman\n2. Bilateral breast cancer, inflammatory breast cancer or carcinoma in situ\n3. Accepted neoadjuvant treatment including chemotherapy, radiotherapy and endocrine therapy\n4. History of organ transplantation\n5. With mental disease\n6. With severe infection or active gastrointestinal ulcers\n7. With severe liver disease (such as cirrhosis), kidney disease, respiratory disease or diabetes\n8. Disease-free period of other malignant tumor is less than 5 years(except cured basal cell skin cancer and cervical carcinoma in situ)\n9. With heart disease\n10. Experimental drug allergy",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
"stdAges": [  
"CHILD",  
"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 eligibility criteria provided for the clinical trial, a patient with a mutation in the ERBB2 gene (commonly referred to as HER2) could be eligible for the trial if the mutation causes the breast cancer to be HER2 positive. Here is the relevant part of the inclusion criteria:  
  
- "Pathological confirmation of triple negative or Her-2 positive or with more than 4 axillary lymph node metastasis"  
  
This indicates that patients with HER2-positive breast cancer are eligible for the trial. An ERBB2 gene mutation that results in HER2 positivity would fit this criterion.   
  
Therefore, if the ERBB2 mutation leads to HER2 positivity in the patient's breast cancer, the patient would be eligible to participate in this clinical trial, provided they meet all other inclusion and exclusion criteria.