# 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:  
A patient with an ERBB2 (also known as HER2) gene mutation \*could\* be eligible for this trial. Inclusion criterion #4 specifically allows for "Her-2 positive" breast cancer.  
  
However, meeting this single criterion doesn't guarantee eligibility. The patient must \*also\* meet all other inclusion criteria and \*not\* meet any of the exclusion criteria. The provided information doesn't tell us if the patient meets these other requirements. Therefore, we can only say they \*might\* be eligible based on the HER2 mutation status alone.