# Clinical Trials Data ERBB2 - Document 37

# Myocet, Docetaxel & Trastuzumab as 1st Line Treatment of Patients With HER-2/Neu Positive Metastatic Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT00250874

"eligibilityCriteria": "Inclusion Criteria:\n\n\* HER-2/neu overexpression assessed by FISH test or with immunohistochemical methods: Dako(the result must be 3+ with dakotest); if the immunohistochemical test results 2+ it is needed a positive FISH test\n\* Female \\< 70yrs\n\* Histologically or cytologically proven breast cancer.\n\* Metastatic or locally advanced breast cancer (clinical stage: III-IV)\n\* Adequate hematological, hepatic, renal and cardiac function, the latter confirmed by echocardiography with FEVS \u226550%\n\* Prior adjuvant chemotherapy if doxorubicin total dose \u2264300 mg/m2, epirubicin total dose \u2264450 mg/m2\n\nExclusion Criteria:\n\n\* History of cardiopathy\n\* Severe hepatic and renal diseases\n\* Brain metastases as the only parameter of disease\n\* Contraindication to the use of corticosteroids as premedication\n\* Acute infectious diseases\n\* Insulin-dependent diabetes\n\* History of other cancers except for adequately treated basal cell skin cancer or in situ carcinoma of the cervix\n\* Concurrent treatment with any other cancer therapy",  
 "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 clinical trial information provided, a patient with an ERBB2 (HER2) gene mutation would potentially be eligible, as long as they meet the specific criteria related to HER2 status. The key inclusion criterion in this trial is "HER-2/neu overexpression assessed by FISH test or with immunohistochemical methods."   
  
To summarize the key points for eligibility based on HER2 status:  
  
1. The patient must have HER-2/neu overexpression. This is typically assessed either by:  
 - A positive FISH test, or  
 - An immunohistochemical method where the result is 3+. If the immunohistochemical test result is 2+, a confirmatory positive FISH test is required.  
  
If a patient with an ERBB2 mutation shows HER-2/neu overexpression via the specified testing methods, they could be eligible for the trial, provided they also meet the other inclusion criteria and none of the exclusion criteria.   
  
Furthermore, since this trial is open to female patients under 70 years old with histologically or cytologically proven metastatic or locally advanced breast cancer (stages III-IV), and assumes adequate hematological, hepatic, renal, and cardiac function, the patient's entire health profile as described would need to be evaluated against these criteria.   
  
If all these conditions align and none of the exclusion criteria apply, the patient with an ERBB2 mutation should be eligible for the trial.