# Clinical Trials Data ERBB2 - Document 54

# Intrathecal Trastuzumab for Leptomeningeal Metastases in HER2+ Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01325207

"eligibilityCriteria": "Inclusion Criteria:\n\nELIGIBILITY CRITERIA\n\n\* HER2 positive (IHC 3+ and/or FISH positive) breast cancer patients with leptomeningeal metastases by MRI or CSF (if MRI is negative).\n\n o Review will be performed for cases not reviewed at Northwestern for confirmation, but will not preclude patients from entering the trial (pathology report is sufficient for registration).\n\* Patients can have concomitant brain metastases as long as they do not require active treatment or have been treated.\n\* Patients with leptomeningeal disease from ependymomas, gliomas, and medulloblastoma will be eligible for phase I\n\* Life expectancy \\> 8 weeks\n\* Normal renal (creatinine \\< 1.5 ULN), liver (bilirubin \\< 1.5 x ULN, transaminases \\< 3.0 x ULN, except in known hepatic metastasis, wherein may be \\< 5 x ULN) and blood counts (WBC \\> 3.0, Neutrophils \\> 1500, platelets \\>100 000, Hemoglobin \\> 10).\n\* LVEF \\> 50%\n\* KPS \\> 50\n\* Age \\> 18 years\n\* Cannot be on systemic agents (chemotherapy) that have CNS penetration unless they develop leptomeningeal metastases while on these agent(s) and have controlled systemic disease. May continue on IV trastuzumab, lapatinib or hormonal agents if controlling systemic disease and developed LM while on therapy. Patients requiring systemic chemotherapy are eligible but will not be able to start treatment until after the first assessment by imaging and cytology.\n\* Patients may need a CSF flow study at the discretion of the treating principal investigator. If a spinal block is seen by CSF flow study or MRI, it will need local RT prior to treatment. Concurrent radiation is not allowed.\n\* Patients should be \\> 2 weeks from RT treatment and all effects of treatment should have resolved\n\* No limit on prior systemic or IT therapies.\n\* CSF sampling to document LM if not documented on MRI.\n\* Must be willing to have an Ommaya reservoir placed.\n\* NO history of any other cancer (except non-melanoma skin cancer or carcinoma in-situ of the cervix) unless in complete remission and off all therapy for the disease for a minimum of 3 years.\n\* Significant medical or psychiatric illness that would interfere with compliance and ability to tolerate treatment as outlined in the protocol.\n\* Women of childbearing potential and sexually active males must commit to the use of effective contraception while on study.\n\* Women may not be pregnant or breast-feeding.\n\* Ability to sign an informed consent; can be signed by family member or health care proxy. Informed consent must be done prior to registration on study.\n\* All patients must have given signed, informed consent prior to registration on study.\n\* No known hypersensitivity to trial medications Note: The eligibility criteria listed above are interpreted literally and cannot be waived.\n\nExclusion Criteria:\n\n- Any deviations from the inclusion criteria",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "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 eligibility criteria provided for the clinical trial, a patient with an ERBB2 gene mutation would be eligible if the specific mutation corresponds to the classification of HER2 positivity as described. It is important to clarify that the ERBB2 gene is also known as the HER2 gene, and mutations or overexpression of this gene can lead to HER2-positive breast cancer.  
  
The inclusion criteria specifically state the need for the cancer to be HER2 positive, which is determined by either IHC (Immunohistochemistry) scoring 3+ or FISH (Fluorescence In Situ Hybridization) being positive. If the patient's ERBB2 mutation results in HER2 positivity as defined by these criteria, they would be eligible for the trial.  
  
Additionally, other criteria such as having leptomeningeal metastases, meeting specific health and treatment conditions, and the absence of other exclusion factors also apply. If all criteria are met, including the confirmation of HER2 positivity, the patient would indeed be eligible for the trial.