# Clinical Trials Data EGFR - Document 117

# Phase II Trial of Double Dose of Icotinib in Treating Brain Metastases From Non-small Cell Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01688713

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histological or cytologic diagnosis of NSCLC\n\* Patients with disease progression after local treatment(WBRT and/or SRS) combined with Icotinib treatment.\n\* Patients with EGFR mutation or the lesions that remains stable for more than 3 months after local treatment(WBRT and/or SRS) combined with Icotinib treatment.\n\* ECOG performance status 0-2\n\* Doctors consider the patients will not benefit from local treatment(WBRT and/or SRS)\n\* Expected survival of greater than 3 months\n\* Age: 18-75 years\n\* The patients with key organs maintenance of basic function: Hemoglobin \u2265 9g/dL, White Blood Cell \u2265 3\u00d7109/L, Neutrophil count \u2265 1.5\u00d7109/L, platelets \u2265 80\u00d7109/L, total bilirubin \\< 1.5 times of the upper normal values, Alanine transaminase (ALT) and aspartate transaminase (AST) \\< 2.5 of the upper normal values, the serum creatinine \\< 1.5 times of the upper normal values\n\* Signed informed consent document on file.\n\nExclusion Criteria:\n\n\* Brain metastasis without local treatment before\n\* Patients without the treatment of Icotinib before or the therapeutic time less than 3 months\n\* More than 3 extracranial organs have metastatic lesions\n\* The patient with other type malignant tumors before\n\* The patient with fertility capacity, but without contraceptive application",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a EGFR gene mutation be eligible for the clinical trial?

Answer:  
A patient with an EGFR mutation \*could\* be eligible, but having the mutation alone is not enough. They must also meet \*one\* of the following two criteria related to Icotinib treatment and local treatment (WBRT and/or SRS):  
  
1. \*\*Disease progression:\*\* They have experienced disease progression \*after\* receiving both local treatment (WBRT and/or SRS) \*and\* Icotinib treatment.  
2. \*\*Stable disease:\*\* Their lesions have remained stable for more than 3 months \*after\* receiving both local treatment (WBRT and/or SRS) \*and\* Icotinib treatment.  
  
In addition to one of the above, they must \*also\* meet all the other inclusion criteria (e.g., NSCLC diagnosis, ECOG performance status, expected survival, age, organ function, informed consent) and \*not\* meet any of the exclusion criteria (e.g., no prior local treatment for brain metastasis, prior Icotinib treatment for at least 3 months, no more than 3 extracranial metastases, no prior malignancies, contraception if applicable).