# Clinical Trials Data EGFR - Document 121

# Icotinib or Whole Brain Irradiation in EGFR-mutant Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01724801

"eligibilityCriteria": "Inclusion Criteria:\n\nPatient who was confirmed stage IV NSCLC with EGFR activating mutation and brain metastases by pathologic histology or cytology.\n\nPatient who brain metastases was shown in MRI or CT scan. Brain metastases lesions should be more than 3.The diameter among these lesions should be more than 1 centimeter.\n\nMales or females aged \u226518 years, \\< 75 years. Eastern Cooperative Oncology Group(ECOG) performance status 0-1. Life expectancy \u226512 weeks. The therapy of surgery,chemotherapy,radiotherapy that the patients were ever received should be more than 2 weeks ago.The patient had recovered from the treatment.\n\nMales and females should be contraceptive during the period of the trial until 8 weeks after the last administration of icotinib.\n\nAble to comply with the required protocol and follow-up procedures, and able to receive oral medications.\n\nWritten informed consent provided.\n\nExclusion Criteria:\n\nPatient was received irradiation of brain. Patient with meningeal metastases were confirmed by MRI or cytology test of cerebrospinal fluid.\n\nPatient is received the treatment of Phenytoin, carbamazepine, rifampicin, phenobarbital, or St. John's Wort.\n\nPatient was received EGFR Tyrosine Kinase Inhibitor or EGFR monoclonal antibody.\n\nInterstitial pneumonia.Pericardial effusion, pleural effusion is uncontrolled .\n\nAny unstable systemic disease (including active infection, uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within the previous year, serious cardiac arrhythmia requiring medication, hepatic, renal, or metabolic disease).\n\nAny significant ophthalmologic abnormality ,especially severe dry eye syndrome ,keratoconjunctivitis sicca,Sjogren syndrome,severe exposure keratitis or any other disorder likely to increase the risk of corneal epithelial lesions.\n\nLack of physical integrity of the upper gastrointestinal tract, or malabsorption syndrome, or inability to take oral medication, or have active peptic ulcer disease.\n\nFemale subjects should not be pregnant or breast-feeding. Adequate hematological function: Absolute neutrophil count (ANC) \u22651.5 x 109/L, and Platelet count \u2265100 x 109/L.\n\nAdequate renal function: Serum creatinine \u2264 1.5 x ULN, or \u2265 50 ml/min. Adequate liver function :Total bilirubin \u00a3 1.5 x upper limit of normal (ULN) and Alanine Aminotransferase (ALT )and Aspartate Aminotransferase (AST )\\< 2.5 x ULN in the absence of liver metastases, or \\< 5 x ULN in case of liver metastases.\n\nThe symptoms of increased intracranial pressure are uncontrolled after dehydration and cortisone treatment.\n\nPatient need increase irradiation dose after routine irradiation(30GY/10f/2w) Patient should treat extra cranial lesions first. Patient assessed by the investigator to be unable or unwilling to comply with the requirements of the protocol.",  
 "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 gene mutation \*could\* be eligible for this trial, but more information is needed. While the inclusion criteria specify "stage IV NSCLC with EGFR activating mutation and brain metastases," several other factors could disqualify a patient:  
  
\* \*\*Brain Metastases Specifics:\*\* The patient must have more than 3 brain metastases lesions, and at least one lesion must be larger than 1 centimeter in diameter.  
\* \*\*Age:\*\* The patient must be between 18 and 75 years old.  
\* \*\*Performance Status:\*\* ECOG performance status of 0-1 and a life expectancy of at least 12 weeks are required.  
\* \*\*Prior Treatment:\*\* Any prior surgery, chemotherapy, or radiotherapy must have been completed more than 2 weeks prior, and the patient must have recovered.  
\* \*\*Prior Brain Irradiation:\*\* Patients who have received brain irradiation are \*excluded\*.  
\* \*\*Other Medications:\*\* Patients taking Phenytoin, carbamazepine, rifampicin, phenobarbital, or St. John's Wort are \*excluded\*.  
\* \*\*Prior EGFR-Targeted Therapy:\*\* Patients who have received an EGFR Tyrosine Kinase Inhibitor or EGFR monoclonal antibody are \*excluded\*.  
\* \*\*Other Health Conditions:\*\* Several other conditions are listed as exclusion criteria, including uncontrolled interstitial pneumonia, pericardial effusion, or pleural effusion; unstable systemic diseases; significant ophthalmologic abnormalities; gastrointestinal issues; pregnancy or breastfeeding; inadequate hematological, renal, or liver function; uncontrolled increased intracranial pressure; and the need for increased irradiation dose after routine irradiation.  
  
In short, having an EGFR mutation is a necessary but not sufficient condition for eligibility. The patient must also meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria.