# 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:  
Based on the provided clinical trial eligibility criteria, a patient with an EGFR gene mutation would generally be eligible for this clinical trial if they meet all the inclusion criteria and do not meet any of the exclusion criteria.  
  
\*\*Key Inclusion Criteria Related to EGFR Mutation:\*\*  
- The patient must have stage IV non-small cell lung cancer (NSCLC) with an EGFR activating mutation and brain metastases confirmed by pathologic histology or cytology.  
  
\*\*Other Inclusion Criteria:\*\*  
- Brain metastases shown on MRI or CT scan with specific lesion requirements.  
- Aged between 18 and 74 years with ECOG performance status 0-1.  
- Life expectancy of at least 12 weeks.  
- Previous surgeries or treatments like chemotherapy or radiotherapy must have been completed more than 2 weeks ago, with the patient fully recovered.  
  
\*\*Exclusion Criteria:\*\*  
- Patients who received irradiation to the brain or have meningeal metastases confirmed by MRI or cytology test of cerebrospinal fluid.  
- Patients who have taken certain medications (e.g., Phenytoin, carbamazepine, rifampicin, phenobarbital, or St. John's Wort).  
- Patients who have had EDTKR Tyrosine Kinase Inhibitor or EGFR monoclonal antibody treatments.  
- Patients with interstitial pneumonia, uncontrolled effusions, unstable systemic diseases, significant ophthalmologic abnormalities, or inadequate renal, liver, and hematological functions.  
  
Therefore, assuming the patient with the EGFR gene mutation does not fall within any exclusion conditions and meets other health criteria, they would likely be eligible for the trial.