# Clinical Trials Data EGFR - Document 73

# Gefitinib With or Without Chemotherapy in Brain Metastases From Non-small Cell Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01951469

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Patient who was confirmed stage IV NSCLC with EGFR activating mutation and brain metastases by pathologic histology or cytology\n2. Patients who had never received therapy (including chemotherapy,WBRT,EGFR-TKI and EGFR monoclonal antibody) after diagnosed brain metastases\n3. Patients had at least three metastatic lesions in brain, or patients with 1-2 intracranial lesions who were not suitable for brain radiotherapy, or patients with 1-2 intracranial lesions who refused brain radiotherapy, at least one intracranial lesion with the longest diameter of \\>5 mm\n4. Adult patients (\u2265 18 years and \u226475 years). ECOG Performance Status 0 or 1 Life expectancy of at least 12 weeks.,Haemoglobin \u00b3 10.0 g/dl, Absolute neutrophil count (ANC) \u00b31.5 x 109/L, platelets \u00b3 100 x 109/L. Total bilirubin \u00a3 1.5 x upper limit of normal (ULN). ALT and AST \\< 2.5 x ULN in the absence of liver metastases, or \\< 5 x ULN in case of liver metastases. Creatinine clearance \u00b3 60ml/min (calculated according to Cockcroft-gault formula).\n5. Patients should be contraceptive during the period of the trial until 8 weeks after the last administration of icotinib.\n6. Able to comply with the required protocol and follow-up procedures, and able to receive oral medications.\n\nExclusion Criteria:\n\n1. Patient was received irradiation of brain. Patient with meningeal metastases were confirmed by MRI or cytology test of cerebrospinal fluid.\n2. Patient is received the treatment of Phenytoin, carbamazepine, rifampicin, phenobarbital, or St. John's Wort.\n3. Patient was received EGFR Tyrosine Kinase Inhibitor or EGFR monoclonal antibody.\n4. Interstitial pneumonia.Pericardial effusion, pleural effusion is uncontrolled .\n5. Any 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).\n6. Any 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.\n7. Lack of physical integrity of the upper gastrointestinal tract, or malabsorption syndrome, or inability to take oral medication, or have active peptic ulcer disease.\n8. The symptoms of increased intracranial pressure are uncontrolled after dehydration and cortisone treatment",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
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"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, but it depends on whether they meet \*all\* of the other inclusion criteria and \*none\* of the exclusion criteria. Simply having the EGFR mutation is not enough.  
  
Here's a breakdown of why:  
  
\* \*\*Inclusion Criteria #1:\*\* Requires stage IV NSCLC \*and\* brain metastases confirmed by specific tests, in addition to the EGFR mutation.  
\* \*\*Other Inclusion Criteria:\*\* There are numerous other requirements related to prior treatment, number and size of brain lesions, age, performance status, blood counts, liver and kidney function, contraception, and ability to comply with the study protocol.  
\* \*\*Exclusion Criteria:\*\* Even if a patient meets all inclusion criteria, they could be excluded if they've had prior brain irradiation, are taking certain medications, have certain medical conditions (like interstitial pneumonia or uncontrolled pericardial/pleural effusion), or have uncontrolled increased intracranial pressure.  
  
Therefore, just knowing the patient has an EGFR mutation is insufficient to determine eligibility. A full review of the patient's medical history and current condition is necessary.