# 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",  
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 "minimumAge": "18 Years",  
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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:  
Based on the inclusion and exclusion criteria provided in the clinical trial information, a patient with an EGFR gene mutation could be eligible for the clinical trial if they meet all the following conditions:  
  
### Inclusion Criteria:  
1. The patient must have confirmed stage IV non-small cell lung cancer (NSCLC) with an EGFR activating mutation and brain metastases.  
2. The patient must not have received any prior therapy (including chemotherapy, whole-brain radiotherapy, EGFR-TKI, or EGFR monoclonal antibody) after being diagnosed with brain metastases.  
3. The patient must have at least three metastatic lesions in the brain, or 1-2 intracranial lesions but unsuitable for or refusing brain radiotherapy, with at least one lesion having a diameter of >5 mm.  
4. The patient must be an adult between 18 and 75 years old with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 and a life expectancy of at least 12 weeks. They must meet certain hematologic and biochemical criteria: Hemoglobin ≥ 10.0 g/dl, Absolute neutrophil count (ANC) ≥ 1.5 x 10^9/L, platelets ≥ 100 x 10^9/L. Total bilirubin ≤ 1.5 x upper limit of normal (ULN), ALT and AST < 2.5 x ULN (or < 5 x ULN if liver metastases are present), and creatinine clearance ≥ 60 ml/min.  
5. The patient must agree to use contraception during the trial and for 8 weeks after the last administration of icotinib.  
6. The patient must be able to comply with protocol requirements and take oral medications.  
  
### Exclusion Criteria:  
1. The patient has received prior irradiation of the brain. Presence of meningeal metastases confirmed by MRI or cytology test of cerebrospinal fluid excludes participation.  
2. The patient is currently receiving treatment with Phenytoin, carbamazepine, rifampicin, phenobarbital, or St. John's Wort.  
3. The patient has previously received an EGFR Tyrosine Kinase Inhibitor or EGFR monoclonal antibody.  
4. Uncontrolled interstitial pneumonia, pericardial effusion, or pleural effusion.  
5. Any unstable systemic diseases, such as active infection, uncontrolled hypertension, unstable angina, recent myocardial infarction, serious cardiac arrhythmia, or significant hepatic, renal, or metabolic disease.  
6. Significant ophthalmologic abnormalities, especially severe dry eye syndrome, keratoconjunctivitis sicca, Sjogren syndrome, severe exposure keratitis, or any disorders increasing the risk of corneal epithelial lesions.  
7. Gastrointestinal issues impacting oral medication integrity or absorption, such as malabsorption syndrome, inability to take oral medication, or active peptic ulcer disease.  
8. Uncontrolled symptoms of increased intracranial pressure after treatment.  
  
If a patient with an EGFR gene mutation meets all the inclusion criteria and none of the exclusion criteria, they would be eligible for this clinical trial.