# Clinical Trials Data EGFR - Document 138

# Erlotinib Hydrochloride or Crizotinib and Chemoradiation Therapy in Treating Patients With Stage III Non-small Cell Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01822496

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically or cytologically confirmed, newly diagnosed non-squamous NSCLC\n\* Unresectable stage IIIA or IIIB disease; patients must be surgically staged to confirm N2 or N3 disease; patients may have invasive mediastinal staging by mediastinoscopy, mediastinotomy, endobronchial ultrasound transbronchial aspiration (EBUS-TBNA), endoscopic ultrasound (EUS), or video-assisted thoracoscopic surgery (VATS)\n\* Patients with any tumor (T) with node (N)2 or N3 are eligible; patients with T3, N1-N3 disease are eligible if deemed unresectable; patients with T4, any N are eligible\n\* Patients must have measurable disease, i.e., lesions that can be accurately measured in at least 1 dimension (longest dimension in the plane of measurement is to be recorded) with a minimum size of 10 mm by computed tomography (CT) scan (CT scan slice thickness no greater than 5 mm)\n\* Patients with a pleural effusion, which is a transudate, cytologically negative and non-bloody, are eligible if the radiation oncologist feels the tumor can be encompassed within a reasonable field of radiotherapy\n\* If a pleural effusion can be seen on the chest CT but not on chest x-ray and is too small to tap, the patient will be eligible; patients who develop a new pleural effusion after thoracotomy or other invasive thoracic procedure will be eligible\n\* The institution's pre-enrollment biomarker screening at a Clinical Laboratory Improvement Amendments (CLIA) certified lab documents presence of known \"sensitive\" mutations in epidermal growth factor receptor tyrosine kinase (EGFR TK) domain (exon 19 deletion, L858) and/or EML4-anaplastic lymphoma kinase (ALK) fusion arrangement; either the primary tumor or the metastatic lymph node tissue may be used for testing of mutations\n\* The institution's pre-enrollment biomarker screening at a CLIA certified lab documents absence of T790M mutation in the EGFR TK domain\n\* Appropriate stage for protocol entry, including no distant metastases, based upon the following minimum diagnostic workup:\n\n \* History/physical examination, including recording of pulse, blood pressure (BP), weight, and body surface area, within 45 days prior to registration\n \* Whole body fludeoxyglucose-positron emission tomography (FDG-PET)/CT (orbits to mid-thighs) within 30 days prior to registration; PET/CT must be negative for distant metastasis\n \* CT scan with contrast of the chest and upper abdomen to include liver and adrenals (unless medically contraindicated) within 30 days prior to registration\n \* Magnetic resonance imaging (MRI) of the brain with contrast (or CT scan with contrast, if MRI medically contraindicated) within 30 days prior to registration\n\* Zubrod performance status 0-1 within 14 days prior to registration\n\* Absolute neutrophil count (ANC) \\>= 1,000 cells/mm\\^3\n\* Platelets \\>= 100,000 cells/mm\\^3\n\* Hemoglobin \\>= 8.0 g/dl (Note: the use of transfusion or other intervention to achieve hemoglobin \\[Hgb\\] \\>= 8.0 g/dl is acceptable)\n\* Serum creatinine \\< 1.5 mg/dL or calculated creatinine clearance \\>= 50 ml/min (by Cockcroft-Gault formula) within 14 days prior to registration\n\* Aspartate aminotransferase (AST)/alanine aminotransferase (ALT) =\\< 2.5 x upper limit of normal (ULN) within 14 days prior to registration\n\* Bilirubin within normal institutional limits within 14 days prior to registration\n\* Negative serum pregnancy test within 14 days prior to registration for women of childbearing potential\n\* Patient must provide study specific informed consent prior to study entry, including consent for mandatory screening of tissue\n\nExclusion Criteria:\n\n\* Prior invasive malignancy (except non-melanomatous skin cancer) unless disease free for a minimum of 730 days (2 years) (for example, carcinoma in situ of the breast, oral cavity, or cervix are all permissible)\n\* Prior systemic chemotherapy for the study cancer; note that prior chemotherapy for a different cancer is allowable\n\* Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields\n\* Atelectasis of the entire lung\n\* Contralateral hilar node involvement\n\* Exudative, bloody, or cytologically malignant effusions\n\* Severe, active co-morbidity, defined as follows:\n\n \* Unstable angina and/or congestive heart failure requiring hospitalization within the last 6 months\n \* Transmural myocardial infarction within the last 6 months\n \* Acute bacterial or fungal infection requiring intravenous antibiotics at the time of registration\n \* Chronic obstructive pulmonary disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy at the time of registration; hepatic insufficiency resulting in clinical jaundice and/or coagulation defects\n \* Acquired immune deficiency syndrome (AIDS) based upon current Centers for Disease Control and Prevention (CDC) definition; note, however, that human immunodeficiency virus (HIV) testing is not required for entry into this protocol; protocol-specific requirements may also exclude immuno-compromised patients\n\* Pregnancy or women of childbearing potential and men who are sexually active and not willing/able to use medically acceptable forms of contraception\n\* Prior allergic reaction to the study drug(s) involved in this protocol",  
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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 \*might\* be eligible for this trial, but it depends on the specific mutation.  
  
The inclusion criteria state:  
  
\* \*\*Presence of known "sensitive" mutations in EGFR TK domain (exon 19 deletion, L858):\*\* This means the patient \*must\* have one of these specific EGFR mutations to be eligible. Just having \*any\* EGFR mutation is not sufficient.  
\* \*\*Absence of T790M mutation in the EGFR TK domain:\*\* The patient \*cannot\* have this specific EGFR mutation. This is often a resistance mutation that develops after treatment with EGFR tyrosine kinase inhibitors.  
  
Therefore, if the patient has either the exon 19 deletion or the L858 mutation, \*and\* does \*not\* have the T790M mutation, then they meet the EGFR mutation requirements for the trial. They would still need to meet all other inclusion criteria and not have any exclusion criteria to be fully eligible.