# Clinical Trials Data ALK - Document 14

# 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",  
 "healthyVolunteers": false,  
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"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a ALK gene mutation be eligible for the clinical trial?

Answer:  
Yes, a patient with an ALK gene mutation would be \*potentially\* eligible for this trial. The inclusion criteria specifically state:  
  
"The institution's pre-enrollment biomarker screening at a 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"  
  
However, having the ALK mutation is only \*one\* of the eligibility requirements. The patient would also need to meet \*all\* of the other inclusion criteria and \*none\* of the exclusion criteria to be eligible. This includes factors such as:  
  
\* \*\*Newly diagnosed, unresectable stage IIIA or IIIB non-squamous NSCLC:\*\* The cancer must be newly diagnosed and of a specific type and stage.  
\* \*\*No T790M mutation:\*\* They must \*not\* have a T790M mutation in the EGFR TK domain.  
\* \*\*Measurable disease:\*\* The tumor must be of a certain size and measurable by CT scan.  
\* \*\*Specific staging and imaging requirements:\*\* They must undergo specific imaging procedures (PET/CT, CT scan, MRI) with results showing no distant metastasis.  
\* \*\*Adequate organ function:\*\* Kidney, liver, and bone marrow function must be within acceptable ranges.  
\* \*\*Performance status and no significant comorbidities:\*\* They must be relatively healthy overall, with no severe active comorbidities.  
  
Therefore, simply having the ALK mutation does not guarantee eligibility. A thorough review of the patient's complete medical history and current condition is necessary to determine final eligibility.