# Clinical Trials Data EGFR - Document 119

# Erlotinib and Surgery in Treating Patients With Head and Neck Cancer That Can Be Removed by Surgery

## Clinical Trial: https://clinicaltrials.gov/study/NCT00601913

"eligibilityCriteria": "DISEASE CHARACTERISTICS:\n\n\* Histologically or cytologically confirmed squamous cell carcinoma (SCC) of the oral cavity, oropharynx, hypopharynx, or larynx\n\n \* SCC of the base of the tongue, pharynx, larynx, or hypopharynx are eligible provided additional biopsy tissue has been already saved in the Tumor Tissue Core Laboratory for research purposes\n \* SCC of the oral cavity or tonsils are eligible only if they already have or agree to have additional biopsies of tumor with adjacent normal tissue available for molecular studies\n\* Candidate for surgical treatment with an established date for surgery with \u2265 a 15 day window of opportunity\n\* Measurable disease by CT scan or MRI\n\* No nasopharyngeal carcinoma\n\nPATIENT CHARACTERISTICS:\n\nInclusion criteria:\n\n\* ECOG performance status 0-2\n\* ANC \\> 1,500/\u00b5L\n\* Platelet count \\> 100,000/\u00b5L\n\* Total bilirubin \\< 1.5 mg/dL\n\* AST/ALT \\< 2 times upper limit of normal\n\* Creatinine \\< 1.5 mg/dL\n\* Not pregnant or nursing\n\* Negative pregnancy test\n\* Fertile patients must use effective contraception\n\nExclusion criteria:\n\n\* Uncontrolled intercurrent illness including, but not limited to, any of the following:\n\n \* Ongoing or active infection or psychiatric illness/social situations that would limit compliance with study requirements\n \* Significant history of uncontrolled cardiac disease (i.e., uncontrolled hypertension, unstable angina, or myocardial infarction within the past 3 months)\n \* Uncontrolled congestive heart failure\n \* Cardiomyopathy with decreased ejection fraction\n\* History of interstitial lung disease (e.g., pneumonitis or pulmonary fibrosis) or evidence of interstitial lung disease on chest CT scan\n\* Clinically significant ophthalmologic abnormalities\n\* HIV positivity\n\nPRIOR CONCURRENT THERAPY:\n\n\* More than 1 year since prior chemotherapy, biologic therapy, or hormonal therapy\n\* No prior radiotherapy or chemotherapy for this tumor\n\* No prior EGFR inhibitors\n\* No concurrent grapefruit or grapefruit juice\n\* No other concurrent investigational agents",  
 "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, having an EGFR gene mutation by itself does not appear to directly affect eligibility for this trial. The criteria do not explicitly mention anything about gene mutations, particularly the EGFR gene mutation, as either an inclusion or exclusion criterion.  
  
However, the eligibility criteria specify that patients must not have received prior EGFR inhibitors, which typically could be prescribed for patients with certain EGFR gene mutations. If the patient with the EGFR mutation has not received prior EGFR inhibitors, and meets all other eligibility criteria (such as having the correct type of squamous cell carcinoma, appropriate lab values, and no history or evidence of conditions listed in the exclusion criteria), they could potentially be eligible for the trial.  
  
It is important to evaluate all aspects of the eligibility requirements, including the disease characteristics, patient characteristics, and prior concurrent therapy conditions, to determine overall eligibility. If the exclusion criteria related to prior EGFR inhibitors are met, then the mutation itself would not disqualify the patient.