# 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:  
This trial is specifically for patients with \*\*squamous cell carcinoma (SCC)\*\* of the head and neck region. The criteria do \*\*not\*\* mention anything about EGFR mutations. While some SCCs \*can\* have EGFR mutations, this trial does not select for them, and having an EGFR mutation is neither an inclusion nor exclusion criterion.  
  
Therefore, a patient \*could\* be eligible for this trial if they have SCC and meet all other criteria, regardless of EGFR mutation status. However, the trial is not designed specifically for patients with EGFR-mutated tumors.