# Clinical Trials Data EGFR - Document 92

# Customized Neoadjuvant Versus Standard Chemotherapy in NSCL Patients With Resectable Stage IIIA (N2)Disease

## Clinical Trial: https://clinicaltrials.gov/study/NCT01784549

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Provision of a signed and dated written informed consent document prior to any study specific procedures.\n\* Age \u226518 years, male or female.\n\* Histologically confirmed NSCLC.\n\* Specimen tumor tissue obtained from mediastinoscopy\n\* ECOG Performance status (PS) 0-1.\n\* Stage IIIA(N2) patients with technical operable disease limited to T1a,b, T2a,b N2 M0; T3 (\\>7 cm) N2 M0.\n\* Medically fit for resection by lobectomy or pneumonectomy.\n\* Radiologically measurable disease (RECIST v1.1 criteria).\n\* Prior surgery for NSCLC if resected \u22655 years.\n\* No prior chemotherapy, targeted-therapy, investigational therapy or radiation for NSCLC.\n\* No uncontrolled medical problems.\n\* No superior vena cava syndrome.\n\* Peripheral neuropathy must be \u2264 grade 1.\n\* Acceptable hematologic and chemistry parameters.\n\* Creatinine clearance \\>50 ml/min.\n\* Female patients or their partners must be surgically sterile or be postmenopausal, or agree to use effective contraception while in trial treatment and for 3 months thereafter.\n\* Female patients with reproductive potential must have a negative pregnancy test (serum or urine) within 72 hours prior to starting treatment.\n\* Patients who are willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures including patient reported measures.\n\nExclusion Criteria:\n\n\* Any evidence of mixed histology including elements of small cell or carcinoid lung cancer.\n\* Stage IIIA patients limited to T3 N1 M0; T3 (invasion) N2 M0; T4 N0, N1 M0.\n\* Any clinically significant GI abnormalities, which may impair intake, transit or absorption of gefitinib, such as the inability to take oral medication.\n\* Current enrollment in another therapeutic clinical trial.\n\* Any psychiatric or cognitive disorder that would limit the understanding or rendering of informed consent and/or compromise compliance with the requirements of this study.\n\* Past medical history of interstitial lung disease, drug-induced interstitial disease, radiation pneumonitis which required steroid treatment or any evidence of clinically active interstitial lung disease\n\* Pre-existing idiopathic pulmonary fibrosis evidence by computerized tomography (CT) scan at baseline.\n\* Uncontrolled or significant CV disease, including: myocardial infarction within 12 months; uncontrolled angina within 6 months; congestive heart failure within 6 months; diagnosed or suspected congenital long QT syndrome;\n\* Any history of clinically significant ventricular arrhythmias (such as ventricular tachycardia, ventricular fibrillation, or Torsades de pointes);\n\* Prolonged QTc interval on pre entry ECG.\n\* Any history of second or third degree heart block (may be eligible if currently have a pacemaker);\n\* Heart rate \\<50/minute on baseline ECG;\n\* Uncontrolled hypertension.\n\* Evidence of prior malignancy (other than non melanoma skin cancer or in situ cervical cancer, or localized and presumed cured prostate cancer with PSA \\< ULN) within the last 3 years.\n\* Other severe acute or chronic medical condition that may increase the risk associated with trial participation or may interfere with the interpretation of trial results and, in the judgment of the investigator.\n\* Patients in whom corticosteroid premedication was contraindicated.\n\* HIV-positive patients on active treatment.\n\* Medications are prohibited at baseline and prior to randomization if they affect the pharmacokinetics of gefitinib, cisplatin, docetaxel, gemcitabine, vinorelbine and pemetrexed or if they are mainly metabolized by CYP3A4.\n\* Patients who are otherwise eligible can be enrolled only if drug substitution is performed with acceptable clinical outcome prior to enrollment: known severe hypersensitivity to gefitinib or other chemotherapeutic agents or any of the excipients of the products.\n\* Pregnancy or breast-feeding.",  
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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 provided eligibility criteria for the clinical trial, there is no explicit mention of an EGFR gene mutation as either an inclusion or exclusion criterion. Therefore, the presence of an EGFR gene mutation does not appear to directly affect a patient's eligibility for this trial. However, you should consider the inclusion and exclusion criteria thoroughly to ensure that all other conditions are met, such as the patient's medical history, performance status, and prior treatments. Additionally, the trial might involve treatments like gefitinib, which could indicate relevance to EGFR mutation status, so consulting with the trial investigator or medical professional involved with the trial would be recommended for clarification on mutation impacts.