# Clinical Trials Data EGFR - Document 69

# Erlotinib Versus Gemcitabine/Cisplatin as (Neo)Adjuvant Treatment in Non-small Cell Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01407822

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Written informed consent provided.\n\* Males or females aged \u226518 years.\n\* Able to comply with the required protocol and follow-up procedures, and able to receive oral medications.\n\* Pathologically diagnosed of non-small cell lung cancer.\n\* Diagnosed as stage IIIA- N2.The diagnosis standard of N2 is as below: Pts with resectable stage IIIA-N2 NSCLC confirmed by mediastinoscopy or EBUS or PET/CT.\n\* EGFR activating mutation in exon 19 or 21 by the biopsy of primary tumor or N2 lymph node.\n\* Measurable disease must be characterized according to RECIST 1.1 criteria.\n\* Measurable lesions are defined as those that can be accurately measured in at least one dimension (longest diameter to be recorded) as \u2265 10mm by spiral CT or MRI scan. The measurable criteria of lymph node is the short axis \u2265 15 mm.\n\* ECOG performance status 0-1.\n\* Life expectancy \u226512 weeks.\n\* Adequate hematological function:Absolute neutrophil count (ANC) \u22651.5 x 109/L, and Platelet count \u2265100 x 109/L, and Hemoglobin \u22659 g/dL (may be transfused to maintain or exceed this level).\n\* Adequate liver function: Total bilirubin \u2264 1.5 x upper limit of normal (ULN);Aspartate aminotransferase (AST), alanine aminotransferase (ALT) \u2264 2.5 x ULN in subjects without liver metastases; \u2264 5 x ULN in subjects with liver metastases.\n\* Adequate renal function:Serum creatinine \u2264 1.25 x ULN, and creatinine clearance \u2265 60 ml/min.\n\* Female subjects should not be pregnant or breast-feeding.\n\nExclusion Criteria:\n\n\* Patients with prior exposure to agents directed at the HER axis (e.g. erlotinib, gefitinib, cetuximab, trastuzumab).\n\* Patients with prior chemotherapy or therapy with systemic anti-tumour therapy (e.g. monoclonal antibody therapy).\n\* Resection of primary malignancy.\n\* EGFR mutation (exon 19 or 21) negative or unknown.\n\* Uncontrolled central nervous system (CNS) metastasis.\n\* History of another malignancy in the last 5 years with the exception of the following:Other malignancies cured by surgery alone and having a continuous disease-free interval of 5 years are permitted; Cured basal cell carcinoma of the skin and cured in situ carcinoma of the uterine cervix are permitted.\n\* Any unstable systemic disease (including active infection, uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within the previous year, serious cardiac arrhythmia requiring medication, hepatic, renal, or metabolic disease).\n\* Known hypersensitivity to Tarceva or gemcitabine or cisplatin.\n\* Eye inflammation or eye infection not fully treated or conditions predisposing the subject to this.\n\* Evidence of any other disease, neurological or metabolic dysfunction, physical examination or laboratory finding giving reasonable suspicion of a disease or condition that contraindicated the use of an investigational drug or puts the subject at high risk for treatment-related complications.",  
 "healthyVolunteers": false,  
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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, a patient with an EGFR gene mutation in exon 19 or 21 would be eligible for the trial, as long as all other inclusion criteria are met and none of the exclusion criteria apply.  
  
The inclusion criteria explicitly state that the patient must have an "EGFR activating mutation in exon 19 or 21 by the biopsy of primary tumor or N2 lymph node." Therefore, having this specific mutation is a requirement for eligibility in the trial.  
  
Please ensure that the patient also meets other listed requirements, such as age, health status, and other specific medical conditions outlined in the criteria. Additionally, check that the patient does not fall into any of the exclusion categories, such as having received prior therapy directed at the HER axis.