# Clinical Trials Data EGFR - Document 84

# Hydroxychloroquine and Gefitinib to Treat Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT00809237

"eligibilityCriteria": "Inclusion Criteria:\n\nFor the lead in phase I study:\n\n1. Pathologically confirmed diagnosis of non-small cell lung cancer.\n2. Stage IIIB with pleural effusion or stage IV disease by the American Joint Committee on Cancer (AJCC) 6th edition staging criteria.\n3. Age equal to or greater than 21 years\n4. Measurable disease, defined according to RECIST criteria\n5. Performance status of 0, 1, or 2 on the Eastern Cooperative Oncology Group(ECOG) Performance Status scale.\n6. At least 2 weeks since prior radiation treatment, chemotherapy or targeted therapy (from the day that protocol treatment begins).\n\n Patients who had been on gefitinib should have a wash out period of two weeks prior to commencement of treatment drugs for this study.\n7. Adequate organ function including the following:\n\n \* Adequate bone marrow reserve:\n\n \* Total white blood cell count (WBC) \\> 3.0 x 109/L\n \* Platelet count \\>100 x 109/L\n \* Hemoglobin \\>8 g/dL\n \* Hepatic:\n\n \* Bilirubin: = 1.25 times the upper limit of normal (ULN)\n \* Alanine transaminase (ALT): = \\<5 times the ULN\n \* Aspartate transaminase (AST): = \\<5 times the ULN\n \* Renal: Serum creatinine =\\< 1.5 times the ULN, or creatinine clearance =\\>60mL/minute as calculated by the standard Cockcroft Gault formula.\n8. Approval for HCQ treatment by an eye doctor, based on a screening eye exam. Examples of disqualifying baseline conditions include macular degeneration and other retinal disease, see exclusion criteria.\n9. Willingness to comply with protocol procedures including the blood-sampling schedule for PK analyses and periodic eye examinations.\n10. Willingness to participate in clinical research as evidenced by their signature on the informed consent form.\n11. Tumor block from subject's biopsy or surgical resection specimen should ideally be available but is not a mandatory requirement for study entry.\n\nFor the phase II study:\n\nInclusion criteria as above, except that:\n\n1. NSCLC patients must be non-smokers and have adenocarcinomas.\n2. Patients who had been on gefitinib should have a wash out period of two weeks prior to commencement of treatment drugs for this study. They must have responded to Gefitinib previously (either CR, PR or SD) for more than twelve weeks to be eligible.\n\nExclusion Criteria:\n\nFor both lead in phase I and phase II study:\n\n1. Current use of hydroxychloroquine for any reason.\n2. Known hypersensitivity to chloroquine, hydroxychloroquine, or any closely related drug.\n3. Known hypersensitivity to erlotinib, gefitinib, or any closely related drug.\n4. Glucose-6-phosphate dehydrogenase (G6PD) deficiency, as HCQ may cause hemolytic anemia in patients with G6PD deficiency.\n5. Cataracts that would interfere with required funduscopic examinations, or severe baseline visual impairment including macular degeneration, retinopathy or visual field changes, or having only one functional eye. All patients must undergo a screening eye exam prior to enrollment.\n6. Pregnant or breastfeeding. HCQ crosses the placenta and use is not recommended during pregnancy except for life-threatening malaria. The effects of gefitinib on a fetus are unknown. For these reasons, female subjects of childbearing age must practice acceptable methods of birth control to avoid pregnancy. Male subjects must also practice acceptable methods of birth control to prevent pregnancy of a partner.\n7. Symptomatic CNS metastases or newly diagnosed CNS metastases that have not yet been definitively treated with radiation and/or surgery. Note that patients with a history of CNS metastases or cord compression are allowable if they have been definitively treated and are clinically stable. Maintenance steroids are allowed but maintenance seizure medication is not allowed.\n8. Prior radiation therapy inclusive of all identified target lesions. Note that prior palliative radiation to bony disease, CNS disease, or a limited thoracic area is allowed, provided that there is measurable disease outside the field and radiation is completed at least two weeks prior to starting treatment and the patient has fully recovered from all side effects.\n9. Any evidence of clinically active interstitial lung disease. Note that patients with chronic, stable radiographic changes who are asymptomatic need not be excluded.\n10. Malignancies within the past 3 years except for adequately treated carcinoma of the cervix or basal or squamous cell carcinomas of the skin.\n11. Although not an absolute exclusion criteria, caution should be exercised in patients with a diagnosis of prophyria or non-light-sensitive psoriasis, as HCQ can significantly exacerbate both of these conditions.\n12. Evidence of any other significant clinical disorder or laboratory finding that makes it undesirable for the patient to participate in the study, in the opinion of the investigator.\n13. Use of any non-FDA approved or investigational agent within 2 weeks of enrolling onto the trial, or failure to recover from the side effects of any of these agents.\n14. Penicillamine use for Wilson's disease or any other indication, as concomitant use with HCQ can increase toxicity to penicillamine.\n15. Concommitant use of anti-convulsants is not allowed.",  
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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:  
This trial has two phases. A patient with an EGFR mutation \*might\* be eligible, but more information is needed and it depends on the phase:  
  
\*\*Phase I:\*\* This phase does \*not\* specifically mention EGFR mutations as an inclusion or exclusion criterion. Therefore, a patient with an EGFR mutation \*could\* be eligible if they meet \*all other\* inclusion criteria and \*none\* of the exclusion criteria.  
  
\*\*Phase II:\*\* This phase requires patients to be non-smokers with adenocarcinoma \*and\* to have previously responded to Gefitinib for more than 12 weeks. Many patients with EGFR mutations respond well to Gefitinib. Therefore, a patient with an EGFR mutation who meets these criteria \*could\* be eligible if they also meet \*all other\* inclusion criteria and \*none\* of the exclusion criteria.  
  
\*\*Key Factors for EGFR Mutation Patients:\*\*  
  
\* \*\*Previous Gefitinib Response (Phase II only):\*\* This is crucial for Phase II eligibility. If the patient hasn't taken Gefitinib or hasn't responded well, they wouldn't be eligible for Phase II.  
\* \*\*Adenocarcinoma and Non-smoker Status (Phase II only):\*\* These are also essential for Phase II.  
\* \*\*Other Inclusion/Exclusion Criteria:\*\* Regardless of EGFR mutation status, the patient must meet all other inclusion criteria (age, staging, organ function, etc.) and must not have any of the exclusion criteria (certain eye conditions, pregnancy, certain other medical conditions, etc.).  
  
  
In summary, having an EGFR mutation doesn't automatically qualify or disqualify a patient. Eligibility depends on the trial phase and meeting all other relevant criteria. The patient should consult with their oncologist and the trial investigators to determine their eligibility.