# Clinical Trials Data EGFR - Document 83

# Everolimus Post Orthotopic Liver Transplant

## Clinical Trial: https://clinicaltrials.gov/study/NCT01998789

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Ability and willingness to provide informed consent and adhere to study regimen\n\* Recipients of primary liver transplant from deceased or living donor\n\* 18 years of age or greater\n\* Lab Model For End-Stage Liver Disease (MELD) score \u2264 30\n\* Abbreviated Modification of Diet in Renal Disease (MDRD) eGFR \u2265 30 mL/min/1.73\n\nKey Exclusion Criteria:\n\n\* Recipient of multiple solid or organ transplant, or have previously received and organ transplant\n\* Women of child-bearing potential unless they are willing to participate in adequate contraception methods as outlined in the study.\n\* HIV infection (results obtained 6 months prior to screening is acceptable)\n\nKey Exclusion-Baseline/ Randamization\n\n\* Severe hypercholesterolemia (\\> 350 mg/dL) or hypertriglyceridemia (\\> 500 mg/dL) within 30 days prior to baseline.\n\* Thrombocytopenia (platelets \\< 50,000/mm3)\n\* Absolute neutrophil count of \\< 1000/mm3 or white blood cell count of \\< 2000/mm3\n\* Subjects in a critical care unit requiring life support measures such as mechanical ventilation, dialysis, requirement of vasopressor agents\n\* Liver allograft is functioning at an unacceptable level as defined by the Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Total Bilirubin levels \\> 3 times upper limit of normal (ULN) and Alkaline Phosphatase (AlkP) and Gamma-glutamyltransferase (GGT) levels \\> 5 times ULN\n\* Diagnosis of autoimmune hepatitis, primary biliary cirrhosis and primary sclerosing cholangitis\n\* Hepatocellular carcinoma with evidence of macrovascular invasion on explanted liver or evidence of extrahepatic spread\n\* Inability to take medications by mouth\n\* Renal insufficiency, as defined by abbreviated MDRD eGFR \\< 30 mL/min/1.73m2, or requirement of dialysis, that does not recover prior to baseline\n\* Episode of acute rejection requiring antibody therapy or more than one steroid treated episode of acute rejection\n\* Subjects with a confirmed spot urine protein/creatinine ratio that indicates \u22651g/24h of proteinuria.\n\* Subtherapeutic trough levels of tacrolimus during the week prior to baseline (subject must have at least one tacrolimus level \u2265 8 ng/mL)\n\* The presence of thrombosis via Doppler ultrasound of the major hepatic arteries, major hepatic veins, portal vein and inferior vena cava.\n\* Presence of clinically significant wound",  
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Question:  
Based on the following clinical trial information, would a patient with a EGFR gene mutation be eligible for the clinical trial?

Answer:  
The clinical trial eligibility criteria provided does not specify any exclusion criteria related to a patient's genetic makeup, such as the presence of an EGFR gene mutation. The inclusion and exclusion criteria seem focused on clinical parameters related to liver transplant recipients, as well as certain health conditions and lab values. Therefore, based on the information given, the presence of an EGFR gene mutation would not make a patient ineligible for this trial. However, it would be important to consult directly with the trial coordinators to verify this, as there may be additional considerations not documented in the provided criteria.