# 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 eligibility criteria do \*\*not\*\* mention EGFR gene mutations. Therefore, having an EGFR mutation would \*not\* automatically exclude a patient from this trial. However, they would still need to meet all other inclusion criteria and not have any of the exclusion criteria.