# Clinical Trials Data EGFR - Document 106

# A Multicenter Clinical Trial of Allopurinol to Prevent Kidney Function Loss in Type 1 Diabetes

## Clinical Trial: https://clinicaltrials.gov/study/NCT02017171

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Male or female subjects with type 1 diabetes continuously treated with insulin within one year from diagnosis\n\* Duration of T1D \u2265 8 years\n\* Age 18-70 years\n\* History or presence of microalbuminuria or moderate macroalbuminuria, or evidence of declining kidney function regardless of history or presence of albuminuria and/or RAS Blocker treatment. Micro- or moderate macroalbuminuria will be defined as at least two out of three consecutive urinary albumin excretion rates \\[AERs\\] or albumin creatinine ratios \\[ACRs\\] taken at any time during the two years before screening or at screening in the 30-5000 mg/24 hr (20-3333 ug/min) or 30-5000 mg/g range, respectively, if not on RASB agents, or in the 18-5000 mg/24 hr (12-3333 ug/min) or 18-5000 mg/g range, respectively, if on RASB agents). Evidence of declining kidney function will be defined as an eGFR (CKD-EPI) decline \u22653.0 ml/min/1.73 m2/year, estimated from the slope derived from all the available serum creatinine measurements (including the one at screening assessment) from the previous 3 years. If at least 3 serum creatinine measures are not available in the previous 3 years, then the slope can be derived from creatinine values from the previous 5 years.\n\* Estimated GFR (eGFR) based on serum creatinine between 40 and 99.9 ml/min/1.73 m2 at screening. The upper and the lower limits should be decreased by 1 ml/min/1.73 m2 for each year over age 60 (with a lower limit of 35 ml/min/1.73m2) and by 10 ml/min/1.73 m2 for strict vegans.\n\* Serum UA (UA) \u2265 4.5 mg/dl at screening\n\nExclusion Criteria:\n\n\* History of gout or xanthinuria or other indications for uric acid lowering therapy such as cancer chemotherapy.\n\* Recurrent renal calculi.\n\* Use of urate-lowering agents within 2 months before screening.\n\* Current use of azathioprine, 6-mercaptopurine, didanosine, warfarin, tamoxifen, amoxicillin/ampicillin, or other drugs interacting with allopurinol.\n\* Known allergy to xanthine-oxidase inhibitors or iodine containing substances.\n\* HLA B\\\*58:01 positivity (tested before randomization).\n\* Renal transplant.\n\* Non-diabetic kidney disease.\n\* SBP\\>160 or DBP \\>100 mmHg at screening or SBP\\>150 or DBP\\>95 mmHg at the end of the run-in period.\n\* Cancer treatment (excluding non-melanoma skin cancer treated by excision) within two years before screening.\n\* History of clinically significant hepatic disease including hepatitis B or C and/or persistently elevated serum liver enzymes at screening and/or history of HBV/HCV positivity.\n\* History of acquired immune deficiency syndrome or human immunodeficiency virus (HIV) infection.\n\* Hemoglobin concentration \\<11 g/dL (males), \\<10 g/dL (females) at screening.\n\* Platelet count \\<100,000/mm3 at screening.\n\* History of alcohol or drug abuse in the past 6 months.\n\* Blood donation in the 3 months before screening.\n\* Breastfeeding or pregnancy or unwillingness to be on contraception throughout the trial.\n\* Poor mental function or any other reason to expect patient difficulty in complying with the requirements of the study.\n\* Serious pre-existing medical problems other than diabetes, e.g. congestive heart failure, pulmonary insufficiency.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"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 inclusion and exclusion criteria for the clinical trial, the eligibility of a patient with an EGFR gene mutation is not directly addressed. The criteria focus on factors such as type 1 diabetes status, kidney function, blood pressure, history of certain medical conditions, medication use, and other specific health indicators. There is no mention of genetic mutations, including EGFR, in the eligibility criteria.  
  
Without specific exclusion criteria related to EGFR gene mutations, it can be inferred that having an EGFR mutation does not automatically disqualify the patient from participation, given that they meet all the other requirements. However, it's always recommended to consult with the trial investigators directly to clarify any genotype-related concerns that might not be explicitly described in the provided criteria.