# Clinical Trials Data EGFR - Document 88

# Comparison Between Tacrolimus (TAC) and Mycophenolate Mofetil (MMF) for Induction of Remission in Lupus Nephritis

## Clinical Trial: https://clinicaltrials.gov/study/NCT01580865

"eligibilityCriteria": "Inclusion Criteria:\n\n\* The patient who had biopsy-proven lupus nephritis class III, IV or V according to the International Society of Nephrology (ISN)/Renal Pathology Society (RPS) 2003 classification (ISN/RPS2003) within 16 weeks of randomization and had ANA or anti-dsDNA positive.\n\* Laboratory tests documented the presence of active nephritis, defined as proteinuria (protein excretion \\>1 g/24 h or spot UPCR \\> 1 for at least two samples) or increased serum creatinine level (\\>0.3 mg/dL of baseline but less than 2.0 mg/dl) with active urinary sediment (any of \\>5 red blood cells/high-power field, \\>5 white blood cells/high-power field, or red blood cell casts in the absence of infection or other causes).\n\* Willingness to participate in the study, and be able to read and provide informed consent.\n\nExclusion Criteria:\n\n\* Severe extra-renal manifestations that may require high-dose steroids or other immunomodulating treatments. The definition of severe extra-renal diseases in this investigation are defined by\n\n \* Active central nervous system deemed to be severe or progressive and/ or associated with significant cognitive impairment leading to inability to provide informed consent and/ or comply with the protocol.\n \* Any condition, including clinical findings or the laboratory results, which the investigators consider the patients have high disease activity and need high dose steroid and immunosuppressive drugs or other therapy depending on investigator opinion.\n \* Severe myocarditis with congestive heart failure or renal failure.\n\* Previous therapy with calcineurin inhibitor or MMF or CYC within the previous 4 months before randomization.\n\* Allergy with macrolide antibiotics.\n\* Uncontrolled hypertension (systolic blood pressure \u2265160mmHg or diastolic blood pressure \u2265100mmHg) at screening day.\n\* Severely deteriorated renal function or rapid progressive crescentic Glomerulonephritis.\n\* Severe myocarditis or cardiomyopathy which may or may not be related to SLE\n\* Patients who have thrombotic microangiopathy who require treatment with plasmapheresis or IVIG.\n\* Severe infection or active TB.\n\* Active hepatitis and evidence of chronic liver disease.\n\* HIV infection.\n\* Diabetes mellitus.\n\* Women who were pregnant or unwilling to use contraception.\n\* Patients who response to steroid (complete remission) during the run in period (4 weeks).\n\* Known hypersensitivity or contraindication to MMF, mycophenolic acid (MPA), tacrolimus, corticosteroids or any components of these drug products.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
"stdAges": [  
"CHILD",  
"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 clinical trial eligibility criteria, there is no mention of an EGFR gene mutation as either an inclusion or exclusion criterion. The eligibility criteria mainly focus on:  
  
- Biopsy-proven lupus nephritis and related laboratory findings  
- Exclusion based on severe extra-renal manifestations, previous therapies, allergies to certain medications, uncontrolled hypertension, severe infections, etc.  
  
An EGFR gene mutation is unrelated to the mentioned criteria. Therefore, a patient with an EGFR gene mutation would not be automatically excluded or included based solely on the mutation, as this factor is not addressed in the trial criteria. However, remember that trial eligibility ultimately will be determined by the trial investigators based on a comprehensive assessment of the patient's overall condition and alignment with all criteria.