# Clinical Trials Data ALK - Document 11

# Vitamin D Repletion in Primary Hyperparathyroidism

## Clinical Trial: https://clinicaltrials.gov/study/NCT01306656

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Diagnosed PHPT, defined by an elevated serum calcium level (we will not study normocalcemic PHPT) with elevated or inappropriately normal PTH levels.\n\* Vitamin D3 less than 30 ng/ml\n\nExclusion Criteria:\n\n\* Patients with familial hyperparathyroid syndromes\n\* Current or past use of the following medications: bisphosphonate within past 2 years, use of lithium or thiazide diuretics, current use of cinacalcet, use of aluminum containing medications, cimetidine, colestipol, or orlistat\n\* Malignancy, except cured basal or squamous cell skin carcinoma or other cured cancers that are at least five years free from recurrence\n\* History or current diagnosis of certain medical diseases (including sarcoidosis, active infectious granulomatous disease, HIV/AIDS, chronic kidney disease (serum creatinine \\> 1.5 mg/dL), liver disease; GI diseases known to affect calcium metabolism; secondary hyperparathyroidism);\n\* We will also exclude patients with calcium above 11.5 mg/dL, urine calcium above 350 mg/day, and active nephrolithiasis because vitamin D repletion could potentially exacerbate hypercalcemia or hypercalciuria\n\* Other exclusions include protected individuals (institutionalized), prisoners, and any other prospective participant who might not be able to give voluntary informed consent.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a ALK gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided eligibility criteria for the clinical trial, there are no specific mentions regarding genetic mutations, including the ALK gene mutation. The inclusion and exclusion criteria focus on conditions such as primary hyperparathyroidism (PHPT), vitamin D levels, certain medical histories, current medications, and specific laboratory values.  
  
Since the ALK gene mutation is not mentioned as either an inclusion or exclusion criteria, the presence of this mutation would not automatically disqualify or qualify a patient for this trial based on the given criteria alone. However, eligibility may still depend on other factors outlined in the criteria, such as serum calcium levels, medication use, or other medical conditions.  
  
For definitive eligibility, it is best for potential participants to consult with the trial's research team or a healthcare provider who can consider all aspects of their medical history in relation to the trial criteria.