# 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:  
This clinical trial is for \*\*primary hyperparathyroidism (PHPT)\*\*. The information provided does \*not\* mention ALK gene mutations as either an inclusion or exclusion criterion. Therefore, having an ALK mutation \*\*does not automatically disqualify\*\* a patient.  
  
However, whether a patient with an ALK mutation is eligible depends on whether they meet \*all\* of the other inclusion criteria and \*none\* of the exclusion criteria. The ALK mutation itself is not a factor mentioned in this particular trial's eligibility requirements.