# Clinical Trials Data ALK - Document 24

# A Study of Different Titration Schedules of ALKS 5461 in Adults With Major Depressive Disorder (MDD)

## Clinical Trial: https://clinicaltrials.gov/study/NCT02085135

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Body mass index of 18-40 kg/m2\n\* Have a diagnosis of MDD\n\* Have a current major depressive episode (MDE) lasting 8 weeks to 24 months\n\* Have been treated with an adequate dose of an approved antidepressant during the current MDE for at least 8 weeks\n\* Have an inadequate response to current antidepressant treatment\n\* Agree to use an approved method of birth control for the duration of the study\n\* Additional criteria may apply\n\nExclusion Criteria:\n\n\* Currently pregnant or breastfeeding\n\* History of or current infection with Hepatitis B Virus, Hepatitis C Virus or Human Immunodeficiency Virus (HIV)\n\* Have experienced hallucinations, delusions, or any psychotic symptoms in the current MDE\n\* Have used opioid agonists (eg, codeine, oxycodone, tramadol, or morphine) or opioid antagonists (eg, naloxone, naltrexone) within 14 days\n\* Have received electroconvulsive therapy treatment within the last 5 years\n\* Have attempted suicide within the past 2 years\n\* Have a history of intolerance, allergy, or hypersensitivity to buprenorphine or opioid antagonists (eg, naltrexone, naloxone)\n\* Have had a significant blood loss or blood donation with 60 days of screening\n\* Additional criteria may apply",  
 "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 clinical trial information, eligibility for the trial is not directly influenced by the presence of an ALK gene mutation. The inclusion and exclusion criteria focus on factors such as body mass index, diagnosis of major depressive disorder (MDD), treatment history, current medication use, and specific health conditions. Therefore, a patient with an ALK gene mutation could potentially be eligible for the trial, as long as they meet all other inclusion criteria and do not fall under any exclusion criteria. However, it is always important to check for any additional criteria that may apply and consult with a healthcare professional or the trial administrators for confirmation.