# Clinical Trials Data ALK - Document 12

# PENTACON Trial: Partial ENdothelial Trepanation in Addition to Anterior Lamellar Keratoplasty in keratoCONus

## Clinical Trial: https://clinicaltrials.gov/study/NCT01145937

"eligibilityCriteria": "Inclusion Criteria:\n\n\* age equal or above 18 years\n\* keratoconus as defined and classified by\n\n \* presence of corneal thinning and protrusion on slit-lamp examination\n \* topographic criteria according to KISA% index (\\>100%)\n \* mean corneal curvature map\n\* decreased best corrected visual acuity due to corneal scarring or contact lens intolerance\n\nExclusion Criteria:\n\n\* prior corneal surgery, cross linking, refractive surgery or other treatment modalities\n\* (localized) corneal thickness \\< 200 \u00b5m\n\* associated corneal endothelial disease on specular microscopy as defined by:\n\n \* \\<1500 endothelial cells per mm2\n \* polymegathism \\> 0.3\n \* pleomorphism \\< 0.6 (all are measurements of endothelial dysfunction)\n\* gross ophthalmic pathology surpassing keratoconus as cause of decreased visual acuity\n\* keratoconus-like disease (keratoglobus, pellucid marginal degeneration)\n\* associated corneal anomalies (microcornea, macrocornea, buphthalmos, Peters syndrome, ICE-syndrome etc.)",  
 "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, the eligibility and exclusion criteria are specific to conditions related to keratoconus and corneal health. There are no criteria related to genetic mutations, such as an ALK gene mutation, that would affect eligibility. Therefore, a patient with an ALK gene mutation would not be disqualified solely for that reason.  
  
However, it's important to note that the presence of an ALK gene mutation does not influence eligibility per the criteria given, as this trial seems to focus on eye-related health criteria rather than genetic markers. To further determine eligibility, the patient would need to meet all the inclusion criteria and not fall under any of the exclusion criteria related to keratoconus and corneal conditions.