# 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:  
This trial is for keratoconus, a corneal disease. The eligibility criteria mention nothing about ALK gene mutations. Therefore, having an ALK gene mutation itself does \*not\* exclude a patient from participating. However, the patient must still meet \*all\* of the other inclusion criteria and \*none\* of the exclusion criteria to be eligible.