# Clinical Trials Data KIT - Document 77

# Uphold Mesh for the Surgical Treatment of Uterine-predominant Prolapse

## Clinical Trial: https://clinicaltrials.gov/study/NCT01559168

"eligibilityCriteria": "Inclusion Criteria:\n\n\* The patient must have given his/her informed and signed consent\n\* The patient must be insured or beneficiary of a health insurance plan\n\* The patient is available for 12 months of follow-up\n\* Patients with symptoms and altered quality of life in relation to uterine or post-hysterectomy vault prolapse\n\* Patients who are receiving the UpholdTM LITE mesh Kit\n\* Female patients \\>= years who have no desire of future pregnancy\n\* Diagnosed with pelvic organ prolapse and \\>= ICS POP-Q Stage 2 Symptomatic Prolapse apical compartment (uterine or vault), associated with ICS POP-Q Stage 2 or 3 Symptomatic Prolapse anterior compartment (point Ba \\>= -1\n\* Patients willing to complete quality of life questionnaire at baseline (pre-procedure) and at 6 weeks, 6 and 12 months post-procedure\n\nExclusion Criteria:\n\n\* The patient is participating in another study\n\* The patient is in an exclusion period determined by a previous study\n\* The patient is under judicial protection, under tutorship or curatorship\n\* The patient refuses to sign the consent\n\* It is impossible to correctly inform the patient\n\* The patient is pregnant, parturient, or breastfeeding\n\* Patients who are not receiving the UpHoldTM LITE mesh Kit\n\* Patients \\< 50 years\n\* Patients qho, according to the clinical judgment of the investigator, are not suitable for this study\n\* Patients who are considering future pregnancies\n\* Patients whose pelvic organ prolapse is a \\<= 1 ICS Stage\n\* Patients requiring Posterior Graft procedure\n\* Patients with known or suspected hypersensitivity to polypropylene\n\* Patients with any pathology which ould compromise implant placement\n\* Patients with any pathology which ould compromise implant placement as mentioned in the device instruction manual\n\* Patients with any pathology that would limit blood supply and compromise healing\n\* Patients with blood coagulation disorder (associated current level coagulation)\n\* Patients with autoimmune connective tissue disease\n\* Patients with upper urinary tract obstruction and renal insufficiency\n\* Patients with local or systemic infection",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
 "minimumAge": "50 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
Based on the provided eligibility criteria for the clinical trial, there is no mention of a KIT gene mutation affecting eligibility. The criteria focus on symptoms and previous conditions related to pelvic organ prolapse, current health conditions, age, pregnancy status, and specific treatment requirements. The presence of a KIT gene mutation does not appear to be an inclusion or exclusion factor in this trial, so a patient with a KIT gene mutation could potentially be eligible, provided all other criteria are met. However, it's important to consult with the clinical trial investigators to confirm eligibility.