# 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:  
This trial is specifically for female patients with uterine or post-hysterectomy vault prolapse who are receiving the UpholdTM LITE mesh Kit. The inclusion/exclusion criteria do \*\*not\*\* mention anything about KIT gene mutations. Therefore, having a KIT gene mutation does \*not\* automatically exclude a patient, but they must meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria to be eligible.