# Clinical Trials Data KIT - Document 67

# Evaluation of Non-cultured Epidermal Cellular Grafting vs Hyaluronic Acid for Repigmenting Vitiligo and Piebaldism

## Clinical Trial: https://clinicaltrials.gov/study/NCT02156427

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Men and women aged over 18 years old with a diagnosis of non-scaring leukoderma that has been stable over the last 2 years (non-segmental, segmental vitiligo and piebaldism)\n\* For non-segmental vitiligo: symmetrical vitiligo lesions, or parts of a lesion. A part of at least 1 cm2 (1 x 1 cm), but preferable 4 cm2 (2x2 cm) and preferably in the center of each lesions (left/right) should be treated.\n\nThe minimum distance between the normal pigmented skin and the test area should preferably be at least 0.5 cm.\n\n\* For segmental vitiligo lesion and piebaldism: all lesions possible if two parts of at least 1 cm2 (1 x 1 cm), but preferably 4 cm2 (2 x 2 cm) in the lesion can be treated. The minimum distance between the 2 areas should be 2 cm and between test areas and to the normal pigmented skin preferably at least 0.5 cm.\n\* Medical treatments of vitiligo failed (in case of vitiligo: at least cream treatment for 6 months).\n\* Absence of infected lesion\n\* Negative serology (HIV-hepatitis B and C- Syphilis)\n\* Without treatment one month for cream and 3 months for phototherapy\n\nExclusion Criteria:\n\n\* Hypersensibility to local anaesthetics or one of the components of the device (trypsin, hyaluronic acid)\n\* Indication against biopsies\n\* Patient with a history of melanoma\n\* Positive serology (ongoing serious systemic disease, herpes, HIV, hepatitis B and C-Syphilis)\n\* Positive pregnancy test\n\* History of keloidal scars and presence of Koebner's phenomenon (type 1 and type 2b)\n\* Infected lesion\n\* Test areas not on fingers and toes vitiligo areas in case of non-segmental vitiligo\n\* Test areas not on facial non segmental vitiligo\n\* Pregnant women, or lactating\n\* Age \\<18years\n\* Major deprived of their freedom by administrative or legal decision, or being the subject of a legal protection measure, or out of state to express their consent",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 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 inclusion and exclusion criteria provided, the presence of a KIT gene mutation is not specified as either an inclusion or exclusion criterion for this clinical trial. The criteria focus primarily on the diagnosis and stability of the vitiligo condition, previous treatment attempts, serology results, hypersensitivity to specific substances, past medical history, and demographic factors.  
  
Unless the KIT gene mutation has direct implications for any of the aforementioned criteria (for instance, affecting the stability of vitiligo or contributing to another exclusion factor such as a history of melanoma), the mutation itself does not automatically disqualify a patient from eligibility. However, it's important to consult with the trial coordinators or principal investigators about any specific genetic considerations that may be relevant to this clinical trial.