# 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:  
This trial is for patients with \*\*leukoderma\*\*, which includes vitiligo and piebaldism, \*not\* specifically for KIT mutations. While KIT mutations can be associated with piebaldism, having the mutation doesn't automatically qualify someone. The patient needs to meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria to be eligible.