# Clinical Trials Data KIT - Document 53

# Effectiveness of Adipose Tissue Derived Mesenchymal Stem Cells as Osteogenic Component in Composite Grafts

## Clinical Trial: https://clinicaltrials.gov/study/NCT01532076

"eligibilityCriteria": "Inclusion Criteria:\n\nPresentation with an isolated proximal humeral fracture after a low-energy trauma (e.g. falling from a standing position) and:\n\n\* indication for open reduction and internal fixation with a proximal humeral locking plate (PHILOS\u00ae, Synthes, Switzerland) after low energy trauma\n\n \* displacement of more than 1 cm between fragments and/or\n \* angulation of 45\u00b0 or more between the fragments and/or\n \* dislocation of the greater tuberosity of 5 mm or more and/or\n \* patient specific factors like high functional demand etc\n\* age \\> 50 years\n\* postmenopausal status (i.e. 12 continuous month without menstruation)\n\* informed consent in surgery and study participation\n\nExclusion Criteria:\n\n\* Psychiatric disorder severely impairing co-operation (dementia mini mental Status (MMS) \\<24, schizophrenia, major depression)\n\* Pathological fractures caused by other conditions\n\* Fracture-related nerve injury\n\* Malignancies under current treatment (i.e. chemotherapy, radiotherapy etc.)\n\* BMI \\<20 kg/m2\n\* Known hypersensitivity to one of the graft components\n\* Participation in a clinical trial within 3 month before enrolment",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "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 clinical trial information, there is no mention of genetic mutations, including KIT gene mutations, in either the inclusion or exclusion criteria. Therefore, a patient with a KIT gene mutation would not be excluded solely based on that mutation. Eligibility would depend on meeting the stated inclusion criteria such as age, postmenopausal status, and specific fracture characteristics, and not falling under the exclusion criteria. If other medical conditions related to the KIT gene mutation cause any of the specified exclusions (like malignancies under current treatment), it might affect eligibility. Otherwise, the KIT gene mutation itself does not appear to impact eligibility for this trial.