# Clinical Trials Data KIT - Document 11

# Use of Autologous Bone Marrow Aspirate Concentrate in Painful Knee Osteoarthritis

## Clinical Trial: https://clinicaltrials.gov/study/NCT01931007

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Male and Female subjects are both eligible\n2. Subjects must be 18 years of age or older\n3. Subjects must have bilateral OA and pain in both knees.\n4. Osteoarthritis may be primary or secondary. Knees must have Kellgren-Lawrence Grades 1-3.\n5. Subjects must have previously tried 6 weeks of one of the following conservative treatments Activity modification, weight loss; physical therapy, anti-inflammatory or injection therapy\n6. Patients can provide written informed consent after the nature of the study is fully explained\n\nExclusion Criteria:\n\n1. Patients with abnormal hematology, serum chemistry, or urinalysis screening laboratory results.\n2. Patients taking anti-inflammatory medications (prescription or over-the-counter), including herbal therapies, within 14 days of baseline visit.\n3. Patients taking anti-rheumatic disease medication (including methotrexate or other antimetabolites) within the 3 months prior to study entry.\n4. Patients receiving injections to the treated knee within 2 months prior to study entry.\n5. Patients who are pregnant or currently breast-feeding children.\n6. Patients with systemic, rheumatic or inflammatory disease of the knee or chondrocalcinosis, hemochromatosis, inflammatory arthritis, arthropathy of the knee associated with juxta-articular Paget's disease of the femur or tibia, ochronosis, hemophilic arthropathy, infectious arthritis, Charcot's knee joint, villonodular synovitis, and synovial chondromatosis.\n7. Patients with ongoing infectious disease, including HIV and hepatitis\n8. Patients with clinically significant cardiovascular, renal, hepatic, endocrine disease, cancer, or diabetes\n9. Patients participating in a study of an experimental drug or medical device within 30 days of study entry.",  
 "healthyVolunteers": true,  
 "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:  
The provided information doesn't mention KIT gene mutations as either an inclusion or exclusion criterion. Therefore, having a KIT gene mutation \*doesn't automatically disqualify\* a patient. They would need to meet all other inclusion criteria and not meet any of the exclusion criteria to be eligible.