# Clinical Trials Data KIT - Document 8

# The MiDAS ENCORE Study

## Clinical Trial: https://clinicaltrials.gov/study/NCT02093520

"eligibilityCriteria": "Inclusion Criteria:\n\n1. 65 years or older and a Medicare beneficiary.\n2. Patients experiencing neurogenic claudication symptoms for at least 3 months duration which has failed to respond or poorly responded to physical therapy, home exercise programs, and oral analgesics.\n3. LSS with neurogenic claudication diagnosed via:\n\n 1. Symptomatic diagnosis and\n 2. Radiologic evidence of LSS with unilateral or bilateral ligamentum flavum \\>2.5mm confirmed by pre-op MRI or CT performed within 12 months of baseline visit.\n4. Patients with comorbid conditions commonly associated with spinal stenosis, such as osteophytes, facet hypertrophy, minor spondylolisthesis, foraminal stenosis, and/or disk protrusion may be included unless the treating physician has determined that the condition is too advanced.\n5. Available to complete 6 month and one year follow-up visits.\n\nExclusion Criteria:\n\n1. ODI Score \\< 31 (0-100 ODI Scale).\n2. NPRS Score \\< 5 (0-10 NPRS Scale).\n3. Prior surgery at any treatment level.\n4. History of recent spinal fractures with current related pain symptoms.\n5. Patients with Grade III or higher spondylolisthesis.\n6. Motor deficit or disabling back and/or leg pain from causes other than LSS neurogenic claudication (e.g., acute compression fracture, metabolic neuropathy, or vascular claudication symptoms, etc.).\n7. Unable to walk \u2265 10 feet unaided before being limited by pain. In this context, 'unaided' means without the use of a cane, walker, railing, wall, another person or any other means of walking assistance.\n8. Patients previously randomized and/or treated in this clinical study.\n9. Patients that have previously received the MILD procedure.\n10. ESI during eight weeks prior to study enrollment.\n11. Epidural lipomatosis (if it is deemed to be a significant contributor of canal narrowing by the physician).\n12. On (or pending) Workman's Compensation or known to be considering litigation associated with back pain.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "65 Years",  
"stdAges": [  
"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 lumbar spinal stenosis (LSS). The inclusion/exclusion criteria do \*\*not\*\* mention anything about KIT gene mutations. Therefore, having a KIT mutation does \*not\* automatically exclude a patient. However, the patient still needs to meet \*all\* other inclusion criteria and \*not\* meet any of the exclusion criteria to be eligible.