# Clinical Trials Data BRAF - Document 23

# Study of Tumor Tissue Samples From Patients With Stage I, Stage II, or Stage III Malignant Melanoma

## Clinical Trial: https://clinicaltrials.gov/study/NCT00991991

"detailedDescription": "OBJECTIVES:\n\n\* Determine the genetic profile of primary melanomas with and without synchronous regional nodal involvement by examining for 1) activating mutations B-Raf and N-Ras associated with melanoma development, and 2) allelic imbalances across the genome.\n\* Compare the genetic profile of primary melanomas from patients with and without lymph node involvement.\n\* Determine the combinations of genetic lesions that correlate with nodal metastasis by adopting a statistical machine learning approach to build a lesion-based classifier for nodal metastasis.\n\nOUTLINE: Laser capture microdissection is performed on the archived tissue samples to isolate melanoma cells. DNA is then purified from the samples and amplified using PCR. Matrix-assisted laser desorption/ionization (MALDI)-time of flight mass spectrometry technology is used to detect mutations of B-Raf and N-Ras. Single nucleotide polymorphism arrays are also performed.\n\nInformation about the patient's demographics (e.g., TNM staging, sex, age, and tissue collection dates) will be gathered by chart review or from the Multidisciplinary Melanoma Conference at University Hospitals tumor conference report in order to match cases."  
 "description": "Information about the patient's demographics (e.g., TNM staging, sex, age, and tissue collection dates) will be gathered by chart review or from the Multidisciplinary Melanoma Conference at University Hospitals tumor conference report in order to match cases."  
 "eligibilityCriteria": "Inclusion Criteria:\n\n\* Node positive Group (experimental group)\n\n \* Primary melanoma \\> 2 mm in depth\n \* Metastasis must be \\> 0.1 mm and detectable by IHC or hematoxylin and eosin (H\\&E) to be considered node positive\n \* Slides and block for primary and node must be archived in UH dermatopathology\n\* Node Negative Group (control group)\n\n \* Primary melanoma \\> 2 mm in depth\n \* A negative sentinel lymph node must be negative by IHC and H\\&E\n\n \* No stage IV disease\n \* No acral and mucosal histology\n \* No history of prior invasive melanoma\n \* Underwent primary excision and sentinel lymph node biopsy within 3 months of each other\n \* Archived tissue available\n \* Slides and block for primary tumor and node biopsy must be archived in University Hospitals Case Medical Center (UH) dermatopathology\n\nExclusion Criteria:\n\n\* Acral and mucosal histology\n\* Previous diagnosis of invasive melanoma\n\* previous chemotherapy or immunotherapy\n\* patients who are found to have stage IV disease during workup",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
"stdAges": [  
"CHILD",  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "Tumor tissue samples from patients with stage I, stage II, or stage III malignant melanoma. Primary care clinic",

Question:  
Based on the following clinical trial information, would a patient with a BRAF gene mutation be eligible for the clinical trial?

Answer:  
Based on the clinical trial information provided, a patient with a BRAF gene mutation would still be eligible for the clinical trial. The study's objectives include determining the genetic profile of primary melanomas, specifically examining activating mutations in B-Raf (BRAF) and N-Ras, which suggests that the presence of a BRAF mutation would not exclude the patient.  
  
Eligibility is focused on other criteria, such as:  
  
- For the node-positive group: Primary melanoma > 2 mm in depth, with nodal metastasis > 0.1 mm detected by IHC or H&E, and archived slides and blocks in UH dermatopathology.  
- For the node-negative group: Primary melanoma > 2 mm in depth, negative sentinel lymph node biopsy by IHC and H&E, and no stage IV disease, acral or mucosal histology, or previous invasive melanoma.  
  
Excluded are patients with acral and mucosal histology, a history of prior invasive melanoma, previous chemotherapy or immunotherapy, and those found to have stage IV disease during workup.  
  
The trial seeks to include patients with stage I, stage II, or stage III malignant melanoma, regardless of their specific genetic mutation profile. Therefore, a patient with a BRAF mutation would meet the genetic study interest and would not be excluded from participation based on the mutation alone.