# Clinical Trials Data BRAF - Document 56

# Phase 2 Study of Neoadjuvant Vemurafenib in Melanoma Patients With Untreated Brain Metastases

## Clinical Trial: https://clinicaltrials.gov/study/NCT01781026

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Biopsy proven metastatic melanoma with the B-raf V600E or V600K mutations.\n\* Untreated brain metastases\n\* At least one cerebral metastasis that is not amenable to stereotactic radiosurgery (SRS) or surgical resection based on size or location OR four or more lesions\n\* Patients may be symptomatic at the time of enrollment, but after any necessary local therapy and/or corticosteroids, the patient should be asymptomatic when vemurafenib is initiated.\n\* Age \\>18\n\* Adequate organ function\n\* ECOG performance status \\< 3\n\* No prior therapies with selective inhibitors of mutated BRAF; other prior therapies must have been administered at least 4 weeks before administration of vemurafenib\n\* Life expectancy of at least 3 months\n\* Understanding and willingness to consent\n\* The use of corticosteroids to control cerebral edema or treat symptoms will be allowed\n\* A history of whole brain radiotherapy for brain metastases is allowed, but any stable lesion that was present at the time of WBRT will NOT be considered evaluable. A minimum of 1 week break will be required between prior WBRT and initiation of vemurafenib therapy.\n\nExclusion Criteria:\n\n\* Presence of leptomeningeal disease based on positive CSF cytology.\n\* History or presence of clinically significant ventricular or atrial dysrhythmias \u2265 Grade 2 (NCI CTCAE, v4.0), Corrected QT (QTc) interval \\>450 ms at baseline or history of congenital long QT syndrome\n\* Uncontrolled medical illness, such as uncontrolled infection, congestive heart failure and MI within 2 months.\n\* Second active, untreated malignancy, which is likely to result in the patient's demise prior to death from uncontrolled melanoma CNS metastases. This will be determined on a case by case basis by the PIs.\n\* Unwillingness to undergo monitoring for a secondary malignancy including clinical dermatologic examinations and head and neck examinations and serial CT scans.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
A patient with \*just\* a BRAF gene mutation is \*\*not automatically eligible\*\*. They need a BRAF V600E \*or\* V600K mutation specifically. Having any other BRAF mutation would exclude them.  
  
In addition to the specific BRAF mutation, they must also meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria to be eligible for this trial.