# Clinical Trials Data BRAF - Document 28

# Radiation Use During Vemurafenib Treatment

## Clinical Trial: https://clinicaltrials.gov/study/NCT02042040

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Age \\> 18 years old\n\* Diagnosis of BRAFV600 mutated Stage IV or unresectable Stage III melanoma\n\* Actively receiving treatment with vemurafenib as single agent and tolerating at least 720 mg bid for one cycle (28 days).\n\* In the opinion of the investigator, patients who are progressing in an area where radiation may provide benefit from either:\n\n \* Symptom control\n \* Oligo-progression, defined as progression in up to 3 areas where focal treatment would provide benefit.\n\* Patients with brain metastases will be allowed provided they meet all of the following criteria:\n\n \* Small, \\< 1cm metastases which are untreated are allowed so long as in the opinion of the investigator they do not require immediate treatment by radiation or surgery\n \* Asymptomatic, treated brain metastases which are stable for 4 weeks prior to study entry are allowed\n \* If patients are requiring steroids for their brain metastases, they must be on a stable dose for two weeks prior to study entry, and maintain that steroid dosing during the radiation treatments\n\* Adequate bone marrow function as defined by: ANC \\> 1.0 k/uL, Platelets \\> 75 k/uL, Hemoglobin \\> 8 g/dL\n\* Adequate hepatic function: Total bilirubin \\< 1.5 times the institutional upper limit of normal, ALT/AST \\< 2.5 times the institutional upper limit of normal\n\* Adequate renal function as defined by serum creatinin \\< 1.5 times the upper limit of normal.\n\* Negative serum pregnancy test at screening for women of child bearing potential within 10 days of starting vemurafenib treatment . Women of non-childbearing potential may be included if they are either surgically sterile or have been postmenopausal for \\> 1 year\n\* Fertile men and women must agree to use an acceptable method of birth control during treatment and for at least 2 months after discontinuation of vemurafenib.\n\* Able and willing to provide informed consent to an approved consent form that conforms to federal and institutional guidelines.\n\nExclusion Criteria:\n\n\* Screening QTc interval \\> 450 msec on EKG\n\* Known HIV positivity or AIDS-related illness, or active HBV, or active HCV.\n\* Any of the following within the 6 months prior to study drug administration: myocardial infarction, severe/unstable angina, coronary/peripheral artery bypass graft, symptomatic congestive heart failure, serious cardiac arrhythmia requiring medication, uncontrolled hypertension, cerebrovascular accident or transient ischemic attack, or symptomatic pulmonary embolism.\n\* Malabsorption disorder that would preclude adequate vemurafenib absorption.\n\* Other medical condition present that in the opinion of the investigator will hinder the subjects ability to complete the study.",  
 "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 a BRAF V600 mutation \*could\* be eligible for this trial, but more information is needed. Having the BRAF V600 mutation is a requirement, but it's not the only one. The patient must also meet \*all\* of the other inclusion criteria and \*none\* of the exclusion criteria.  
  
Here's a breakdown of why simply having the mutation isn't enough:  
  
\* \*\*Stage of Melanoma:\*\* The patient needs to have Stage IV or unresectable Stage III melanoma.  
\* \*\*Current Treatment:\*\* They must be actively receiving and tolerating vemurafenib at a specific dosage.  
\* \*\*Progression of Disease:\*\* Their melanoma needs to be progressing in a way that radiation therapy could provide benefit (symptom control or oligo-progression). Specifics about the patient's disease progression are needed.  
\* \*\*Brain Metastases (If Applicable):\*\* If the patient has brain metastases, they must meet further criteria regarding size, treatment status, and symptoms.  
\* \*\*Lab Values:\*\* Adequate bone marrow, hepatic, and renal function is required, as evidenced by specific lab results.  
\* \*\*Pregnancy and Birth Control:\*\* Requirements for women of childbearing potential and fertile men and women must be met.  
\* \*\*Other Health Conditions:\*\* The patient must not have any other medical condition that would prevent them from completing the study.  
\* \*\*Exclusion Criteria:\*\* The patient must not meet any of the exclusion criteria (e.g., specific heart conditions, HIV/AIDS, HBV, HCV, recent major medical events).  
  
In short, the BRAF V600 mutation is a necessary but insufficient condition for eligibility. A physician would need to evaluate the patient's full medical history and current condition to determine their eligibility.