# Clinical Trials Data BRAF - Document 2

# Trametinib With or Without Whole Brain Radiation Therapy in Treating Patients With Brain Metastases

## Clinical Trial: https://clinicaltrials.gov/study/NCT02015117

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically confirmed cancer with measurable or evaluable brain metastases by computed tomography (CT) or magnetic resonance imaging (MRI); MRI is preferred, but a CT scan is acceptable for patients that are unable to have an MRI\n\* Eastern Cooperative Oncology Group (ECOG) performance status 0 -1\n\* All prior treatment- related toxicities must be Common Terminology Criteria for Adverse Events (CTCAE) (version 5.0) =\\< grade 1 (except alopecia) at the time of enrollment\n\* Absolute neutrophil count \\>= 1.5 x 10\\^9/L\n\* Hemoglobin \\>= 9 g/dL\n\* Platelets \\>= 100 x10\\^9/L\n\* Prothrombin time (PT)/international normalized ratio (INR) and partial thromboplastin time (PTT) =\\< 1.5 x upper limit of normal (ULN) unless using warfarin for therapeutic anti-coagulation\n\* Albumin \\>= 2.5 g/dL\n\* Total bilirubin =\\< 1.5 x ULN\n\* Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) =\\< 2.5 x ULN\n\* Creatinine =\\< 1.5 ULN or calculated creatinine clearance \\>= 50 mL/min or 24-hour urine creatinine clearance \\>= 50 mL/min; calculated by the Cockcroft-Gault formula\n\* Left ventricular ejection fraction (LVEF) \\>= 50% by echocardiogram (ECHO) or multigated acquisition scan (MUGA); same method as used at baseline must be use throughout the study, ECHO is the preferred method\n\* Life expectancy of at least 3 months in the opinion of investigator\n\* Able to swallow and retain orally administered medication and does not have any clinically significant gastrointestinal abnormalities that may alter absorption such as malabsorption syndrome or major resection of the stomach or bowels\n\* Ability to provide written informed consent obtained prior to participation in the study and any related procedures being performed\n\* Women of child-bearing potential (WOCBP) must have a negative pregnancy test within 14 days prior to start of study treatment, and counselled on contraception/abstinence while receiving the study treatment; urine or serum human chorionic gonadotropin (HCG) is an acceptable pregnancy assessment; women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation; women of child-bearing potential must have a negative serum or urine pregnancy test within 14 days prior to randomization; should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this study, she should inform her treating physician immediately; men treated or enrolled on this protocol must also agree to use adequate contraception prior to the study, for the duration of study participation, and 4 months after completion of trametinib administration\n\nExclusion Criteria:\n\n\* Prior radiation therapy to the whole brain (prior stereotactic radiosurgery or fractionated stereotactic radiation therapy to focal areas is allowed)\n\* Evidence of leptomeningeal metastases\n\* Urgent need of treatment to prevent acute neurologic deterioration\n\* Radiosensitive primary tumor such as small cell lung cancer, germ cell tumors, lymphoma, leukemia, or multiple myeloma\n\* History of another malignancy that makes determination of the source of the brain metastases uncertain\n\* History of interstitial lung disease or pneumonitis\n\* Any major surgery, extensive radiotherapy, chemotherapy with delayed toxicity, biologic therapy, or immunotherapy within 14 days prior to enrollment and/or daily or weekly chemotherapy with the potential for delayed toxicity within 14 days prior to enrollment\n\* Use of other anti-cancer therapies within five half-lives from the previous dose of the prior anti-cancer therapy preceding enrollment and during the study\n\* Symptomatic or untreated spinal cord compression\n\* Have a known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to trametinib, or excipients or to dimethyl sulfoxide (DMSO)\n\* Current use of a prohibited medication; the following medications or non-drug therapies are prohibited:\n\n \* Other anti-cancer therapy while on study treatment; (note: megestrol \\[Megace\\] if used as an appetite stimulant is allowed)\n \* Concurrent treatment with bisphosphonates is permitted; however, treatment must be initiated prior to enrollment; prophylactic use of bisphosphonates in patients without bone disease is not permitted, except for the treatment of osteoporosis\n \* Concurrent use of all herbal supplements is prohibited during the study (including, but not limited to, St. John's wort, kava, ephedra \\[ma huang\\], gingko biloba, dehydroepiandrosterone \\[DHEA\\], yohimbe, saw palmetto, or ginseng)\n\* Drugs that potently inhibit or induce CYP3A4 should be administered with caution; below are a few examples of the agents:\n\n \* Drugs that may increase exposure of trametinib (CYP3A4 inhibitors):\n\n \* Antivirals: amprenavir, atazanavir, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir\n \* Antibiotics: clarithromycin, erythromycin, telithromycin, troleandomycin\n \* Antifungals: fluconazole, itraconazole, ketoconazole, voriconazole\n \* Antidepressants: nefazodone\n \* Calcium channel blockers: mibefradil, diltiazem, verapamil\n \* Miscellaneous: aprepitant\n \* Drugs that may decrease exposure of trametinib (CYP3A4 inducers)\n\n \* Antivirals: efavirenz, nevirapine\n \* Antibiotic: rifampin\n \* Anticonvulsants: carbamazepine, phenobarbital, phenytoin\n \* Caution should be exercised when dosing trametinib concurrently with medications with narrow therapeutic windows that are substrates of CYP2C8; below are a few examples of the agents\n\n \* Drug metabolism potentially affected by trametinib resulting in increased exposure of these substrates\n\n \* 3-hydroxy-3-methyl-glutaryl-CoA (HMG CoA)-reductase inhibitors: cerivastatin\n \* Thiazolidinediones: rosiglitazone, pioglitazone\n \* Miscellaneous: chloroquine, zopiclone, repaglinide\n \* As part of the enrollment/informed consent procedures, the patient will be counseled on the risk of interactions with other agents, and what to do if new medications need to be prescribed or if the patient is considering a new over-the-counter medicine or herbal product\n\* History or current evidence/risk of retinal vein occlusion (RVO) or retinal pigment epithelial detachment (RPED):\n\n \* History of RVO or RPED, or predisposing factors to RVO or RPED (e.g., uncontrolled glaucoma or ocular hypertension, uncontrolled systemic disease such as hypertension, diabetes mellitus, or history of hyperviscosity or hypercoagulability syndromes)\n \* Visible retinal pathology as assessed by ophthalmic exam that is considered a risk factor for RVO or RPED such as evidence of new optic disc cupping, evidence of new visual field defects, and intraocular pressure \\> 21 mm Hg\n\* History or evidence of cardiovascular risk including any of the following:\n\n \* LVEF \\< lower limit of normal (LLN)\n \* A QT interval corrected for heart rate using the Bazett's formula QTcB \\>= 480 msec\n \* History or evidence of current clinically significant uncontrolled arrhythmias (exception: patients with controlled atrial fibrillation for \\> 30 days prior to registration are eligible)\n \* History of acute coronary syndromes (including myocardial infarction and unstable angina), coronary angioplasty, or stenting within 6 months prior to registration\n \* History or evidence of current \\>= class II congestive heart failure as defined by the New York Heart Association (NYHA) functional classification system\n \* Treatment-refractory hypertension defined as a blood pressure of systolic \\> 140 mmHg and/or diastolic \\> 90 mmHg which cannot be controlled by anti-hypertensive therapy\n \* Patients with intra-cardiac defibrillators\n \* Known cardiac metastases\n\* Known hepatitis B virus (HBV), or hepatitis C virus (HCV) infection (with the exception of chronic or cleared HBV and HCV infection, which will be allowed); patients with human immunodeficiency virus (HIV) are not eligible if on anti-retroviral medications\n\* Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements\n\* Pregnancy or breastfeeding (women of childbearing potential should be advised to avoid pregnancy and use effective methods of contraception; men with a female partner of childbearing potential must have either had a prior vasectomy or agree to use effective contraception; if a female patient or a female partner of a patient becomes pregnant while the patient receives trametinib, the potential hazard to the fetus should be explained to the patient and partner (as applicable); radiation therapy is also contraindicated in pregnancy\n\* Unable to reliably be immobilized for safe administration of whole brain radiation therapy",  
 "healthyVolunteers": false,  
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"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:  
This trial description does \*\*not\*\* specify BRAF mutation status as either an inclusion or exclusion criterion. Therefore, having a BRAF mutation would \*not\* automatically disqualify a patient. They would need to meet all other inclusion criteria and not have any of the exclusion criteria to be eligible.