# Clinical Trials Data ALK - Document 28

# Study of Dalantercept and Sorafenib in Patients With Advanced Hepatocellular Carcinoma

## Clinical Trial: https://clinicaltrials.gov/study/NCT02024087

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically confirmed, locally advanced or metastatic HCC.\n\* Child-Pugh Score A (5-6)\n\* At least one target lesion that has not been treated with local therapy and is measurable by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1\n\* Eastern Cooperative Oncology Group (ECOG) performance status of 0-1.\n\* Life expectancy of at least 12 weeks.\n\* Able to tolerate oral therapy.\n\* Appropriate clinical laboratory values within 72 hours prior to study day 1:\n\* Females of child bearing potential (defined as sexually mature women who have not undergone hysterectomy or bilateral oophorectomy, or are not naturally postmenopausal \u2265 24 consecutive months) must have negative urine or blood pregnancy test prior to enrollment and use adequate birth control methods (abstinence, oral contraceptives, barrier method with spermicide, or surgical sterilization) during study participation. Males must agree to use a latex condom during any sexual contact with females of child bearing potential while participating in the study and for 12 weeks following the last dose of dalantercept, even if he has undergone a successful vasectomy. Patients must be counseled concerning measures to be used to prevent pregnancy and potential toxicities prior to the first dose of dalantercept.\n\nExclusion Criteria:\n\n\* Mixed tumor histology\n\* Prior systemic therapy for metastatic disease.\n\* Adjuvant therapy \\< 6 months prior to study day 1.\n\* Prior treatment with dalantercept or other agent targeting the ALK1 pathway.\n\* Prior treatment with sorafenib or other RAF/VEGF targeted therapies.\n\* Hepatic radiation, chemoembolization, and radiofrequency ablation \\< 4 weeks prior to study day 1.\n\* Palliative radiation therapy to metastatic sites of disease \\< 2 weeks prior to study day 1.\n\* Interferon therapy \\< 4 weeks prior to study day 1.\n\* Uncontrolled Hepatitis B despite appropriate therapy.\n\* Clinically significant pulmonary, endocrine, neurologic, hematologic, gastrointestinal (GI), autoimmune, psychiatric or genitourinary disease unrelated to HCC that in the judgment of the investigator should preclude treatment with dalantercept or sorafenib.\n\* Known HIV infection.\n\* Clinically significant cardiovascular risk\n\* Clinically significant active pulmonary risk\n\* Known active gastrointestinal (GI) bleeding.\n\* Known bleeding diathesis Known history of hereditary hemorrhagic telangiectasia (HHT).\n\* History of another primary cancer, with the exception of:\n\n 1. Curatively resected non melanoma skin cancer.\n 2. Curatively treated cervical carcinoma in situ.\n 3. Other primary solid tumor with no known active disease in the opinion of the investigator that will not affect patient outcome in the setting of current HCC diagnosis.\n\* Major surgery within 4 weeks prior to study day 1 Active infection Anti-coagulation therapy Concomitant treatment with potent CYP3A4 inducers\n\* Peripheral edema \u2265 grade 2 within 2 weeks prior to study day 1.\n\* History of recurrent ascites requiring paracentesis within 4 weeks of study day 1.\n\* History of severe (using the National Cancer Institute Common Toxicity Criteria for Adverse Events, version 4.0 \\[NCI-CTCAE\\] v4 current minor version \u2265 grade 3) allergic or anaphylactic reaction or hypersensitivity to recombinant proteins or excipients",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
This trial is for Hepatocellular Carcinoma (HCC), or liver cancer. The criteria mention nothing about ALK gene mutations as an inclusion criteria. While the exclusion criteria mention "Prior treatment with dalantercept or other agent targeting the ALK1 pathway", this does \*not\* mean the trial is \*for\* patients with ALK mutations. It simply means that patients who have \*already\* received a drug targeting ALK1 are excluded.  
  
Therefore, simply having an ALK gene mutation does \*not\* automatically qualify a patient for this trial. They must also meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria. Specifically, they would need to have HCC that meets the other listed requirements.