



HIV-RELATED CANCER RESEARCH STUDY NOW ENROLLING STUDY PARTICIPANTS



AMC 042: Trial of Imatinib Mesylate (Gleevec) to Treat Kaposi's Sarcoma

Imatinib is a signal transduction inhibitor approved by the FDA for the treatment of newly diagnosed chronic myeloid leukemia after failure of interferon-alpha therapy. Since approval, it has been shown to be beneficial in treating gastrointestinal stromal tumor. Imatinib inhibits both platelet-derived growth factor (PDGF) and c-kit receptors, which may have utility in treating Kaposi's sarcoma (KS).

AMC 042 is a Phase II, open-label study designed to provide clinical response data for imatinib in persons with HIV/AIDS-related Kaposi's sarcoma. The study will also investigate mechanisms of resistance and toxicity and potential predictors of response. Study participants will receive imatinib for 6 months and may be eligible to extend study treatment for an additional 6 months, depending on initial response. At the end of the 12-month study period, further treatment will be at the discretion of the investigator. Clinical and laboratory evaluations will be performed prior to the initiation of study medication and at Days 1, 2, 8, 15, 16, and 29, then every 28 days thereafter for 6 to 12 months.

This study is open to HIV-infected men and women with KS, age 18 and older, who are interested and meet protocol eligibility. Major eligibility requirements are:

Inclusion Criteria

- Biopsy-proven KS involving the skin, lymph nodes, oral cavity, gastrointestinal (GI) tract and/or lungs. GI and pulmonary involvement must be asymptomatic or minimally symptomatic and not require systemic cytotoxic therapy. At least 5 measurable, previously non-radiated, skin lesions must be present, with 3 lesions greater or equal to 5 x 5 mm and accessible for 4 mm punch biopsy.
- Adequate hematology and hepatic function: hemoglobin ≥ 8 g/dl, ANC ≥ 1000 cells/mm³, platelets $\geq 75,000$ /mm³, creatinine < 1.5 x ULN or clearance > 60 ml/min, total bilirubin normal, AST/ALT ≤ 2.5 x ULN (some variance allowed).
- Antiretroviral (ARV) therapy is required except for those who have exhausted all available treatment options.
- Life expectancy of 3 months or more.
- No previous imatinib therapy.

Exclusion Criteria

- Patient is less than or equal to 5 years free of another primary malignancy *except* if the other primary malignancy is not currently clinically significant and does not require active intervention or if it is basal cell skin cancer or cervical carcinoma in situ. Existence of any other malignant disease is not allowed.
- Patients may not have had anti-neoplastic treatment for KS (including chemo-, radiation, biological or investigational therapy) within 4 weeks (or 6 weeks for nitrosourea or mitomycin-C) of study entry.
- Previous local therapy of a KS indicator lesion within 60 days, unless progression since treatment.
- Current active opportunistic infection (OI) or severe and/or life-threatening medical disease, including cardiac disease (congestive heart failure, heart attack within 6 months of study) or active hepatitis or cirrhosis (known hepatitis C infection with no or minimal fibrosis on liver biopsy is allowed).
- Female patients who are pregnant or breast-feeding.

AMC 042 is being conducted under the direction of Ronald Mitsuyasu MD at the UCLA CARE Center. This study is sponsored by the National Cancer Institute and coordinated by the AIDS Malignancy Consortium (AMC)

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