CHML TREATMENT

Overview

This is a clinical study to evaluate efficacy of Cytotroic Heterogenous Molecular Lipids (CHML), in patients with advanced or metastatic disease. Response to treatment, duration of response, and survival will be followed.

Patients are treated with 7 mg/kg of CHML, one time per day, 5 to 7 days per week by Intravenous drip (IV), Arterial infusion, local injection, or a combination of these methods.

Duration

Treatment will continue for 2 weeks, followed by 2 to 4 weeks off, for a total of 2 to 3 cycles.

Recruitment Detail

Type:	Active Accrual Of New Subjects
Gender:	Male & Female
Referral Letter Required:	No
Population Exclusion:	None

Eligibility Criteria

Histologically confirmed diagnosis or biopsy for carcinoma, myeloma; melanoma, sarcoma; melanocarcinoma, lymphoma; or, solid tumor(s) including the following sites: breast, prostate, pancreas, colon, rectum, lung, stomach, liver.

- Measurable tumor size by X-ray, CT, MRI, or ultrasonography
- Performance status / scale: ECOG 0 – 2. (Karnofsky: > 60)
- Estimation for survival time: >3 months
- Age: 18 – 73 years old
- Function of major organs (e.g. heart, lung, liver, kidney, stomach, colon and bone marrow) within normal range (according to World Health Organization guidelines)

Disease Characteristics

Primary, recurrent or metastatic cancer, including lymphoma and leukemia.

Special Requirements for Breast Cancer

- Urgent local complications resolved prior to entry (e.g. untreated hypdronephrosis, impending spinal cord compressions)
- Severe bone pain unresponsive to analgesics

- Liver tumor replacement less than 50% total liver surface

Special Requirements for Prostate Cancer

- Leuprolide continued in non-orchiectomized patients. At least 4 weeks since flutamide or other antiandrogen.
- PSA at least 20 ng/mL (if no measurable or evaluable disease)

Prior/Concurrent Therapy

Biological Therapy:	Not specified.
Chemotherapy:	At least 4 weeks since last treatment (6 weeks since nitrosoureas or mitomycin) are recovered. No concurrent chemotherapy.
Endocrine Therapy:	The use of corticosteroids is permitted, if necessary, however it is recommended that the smallest dose be used and recorded.
Radiotherapy:	No prior radiotherapy to more than 40% of bone marrow. At least 4 weeks since radiotherapy and recovered. At least 6 weeks since bone-seeking radioisotopes.
Surgery:	Recovered from prior surgery.

Patient Characteristics

Hematopoietic:	Absolute granulocyte count greater than 1,500/mm Platelet count great than 50,000/mm^3 Hemoglobin less than or equal to 6.5 mg/dl
Hepatic:	SGPT and SGOT less than 5 times upper limit of normal Bilirubin less than 2.5 times normal AST and ALT less than 3 times normal PT/PTT normal No coagulopathy
Renal:	Creatine concentration in serum not higher than 2.5 mg/ml Cretonne clearance (measured) at least 50 mL No active renal disease
Cardiovascular:	No Symptomatic heart disease including ▪ Significant arrhythmias (e.g. greater than first-degree heart block) ▪ No unstable or newly diagnosed angina pectoris ▪ Less than fully compensated congestive cardiac failure ▪ No myocardial infarction within 6 months

- No class II-IV congestive heart failure
- Uncontrolled and symptomatic atrial dysrhythmia, EXCEPT sinus, bradycardia or sustained ventricular tachycardia

Pulmonary:

Forced vital capacity at least 1,000 mL
No major uncontrolled active infection (unless due to obstructed bronchus)

Other:

Exclusion Criteria

- Patients with severe allergic reactions to iodine contrast which can not be controlled by premedication with antihistamines and steroids are not eligible, as hepatic angiograms are required for this procedure.
- Must be HIV negative
- No active infection requiring antibiotics within 7 days prior to entry
- No patients with known chronic heart failure and serious lung disease, such as server COPD
- Patients must be aware of the neoplastic nature of his/her illness, the experimental nature of the therapy, alternative treatments, potential benefits, and risks.
- Patients must not have a history of veno occlusive disease
- No bacterial colonization secondary to
    - Percutaneous nephrostomy tube, Ileal pouch, Indwelling urinary catheter
- No peripheral neuropathy greater than grade II
- Patients with hypertension are excluded (unless blood pressure is adequately controllable)
- No requirement for therapeutic warfarin or heparin
- No history of uncontrolled seizures within 1 year and no requirement for anticonvulsants
- Not pregnant or nursing (negative beta-HCG required for fertile women)
- Patient must be willing to sign an informed consent
- Effective contraception required for fertile patients during and for 2 months following protocol therapy
- No history of diabetes mellitus within 6 months of enrollment
- No patients with high medical or psychiatric risk, or non-malignant systemic disease which would, in the opinion of the investigator, make therapy with an investigational drug unwise
- Female patients must not be pregnant or breast-feeding an infant, and either incapable of becoming pregnant or currently using contraceptive methods.
- Male patients should use appropriate contraception during the study, and for at least 4 weeks post treatment

Special Instruction

Many protocols may be potentially hazardous and are intended only for use by clinical specialists in carefully structured settings, and may not prove to be more effective than standard treatment. Dose and schedule modifications may be required for patients who develop gastrointestinal, hematologic, neurologic, and biochemical (renal, hepatic, etc.) and/or other abnormalities and the administration of therapy.

Disease Category

Neoplasms