



## Mesothelioma Articles



### Vaccine Therapy and GM-CSF in Treating Patients With Acute Myeloid Leukemia, Myelodysplastic Syndromes, Non-Small Cell Lung Cancer, or Mesothelioma

**This study is currently recruiting patients.**

Verified by National Cancer Institute (NCI) November 2006

|                                       |  |
|---------------------------------------|--|
| <b>Sponsors and Collaborators:</b>    | <b>Memorial Sloan-Kettering Cancer Center</b><br>National Cancer Institute (NCI) |
| <b>Information provided by:</b>       | National Cancer Institute (NCI)  |
| <b>ClinicalTrials.gov Identifier:</b> | NCT00398138  |

## Purpose

**RATIONALE:** Vaccines made from peptides may help the body build an effective immune response to kill cancer cells. Biological therapies, such as GM-CSF, may stimulate the immune system in different ways and stop cancer cells from growing. Giving vaccine therapy together with GM-CSF may kill more cancer cells.

**PURPOSE:** This phase I trial is studying vaccine therapy together with GM-CSF to see how well it works in treating patients with acute myeloid leukemia, myelodysplastic syndromes, non-small cell lung cancer, or [mesothelioma](#).

| Condition  | Intervention  | Phase   |
|--|---|---------|
| Leukemia<br>Lung Cancer<br>Malignant Mesothelioma<br>Myelodysplastic/Myeloproliferative Diseases<br>Peritoneal Cavity Cancer | Drug: WT1 peptide vaccine<br>Drug: incomplete Freund's adjuvant<br>Drug: sargramostim<br>Procedure: biological therapy<br>Procedure: diagnostic test<br>Procedure: flow cytometry<br>Procedure: immunoenzyme techniques<br>Procedure: non-specific immune-modulator therapy<br>Procedure: non-tumor cell derivative vaccine<br>Procedure: polymerase chain reaction<br>Procedure: vaccine therapy | Phase I |

MedlinePlus related topics: Anemia; Blood and Blood Disorders; Bone Marrow Diseases; Cancer; Cancer Alternative Therapies; Leukemia, Adult Acute; Leukemia, Adult Chronic; Leukemia, Childhood; Lung Cancer; Mesothelioma

Genetics Home Reference related topics: Anemia; Blood and Blood Disorders; Cancer

Study Type: Interventional

Study Design: Treatment

Official Title: Pilot Trial of a WT-1 Analog Peptide Vaccine in Patients With Thoracic and Myeloid Neoplasms

Further study details as provided by National Cancer Institute (NCI):

Primary Outcomes: Safety and immunogenicity; Immune response as measured by T-cell proliferative response, delayed-type hypersensitivity against WT-1 peptides, or ELISPOT

Secondary Outcomes: Antileukemic effects; Clinical and molecular response; Antitumor response by CT scan based on RECIST criteria; Toxicity as measured by NCI CTC v. 3.0

Expected Total Enrollment: 20

Study start: October 2006

#### OBJECTIVES:

##### Primary

- Determine the safety and immunogenicity of the WT-1 vax peptide vaccine in patients with acute myeloid leukemia, myelodysplastic syndromes, non-small cell lung cancer, or mesothelioma.

##### Secondary

- Determine the antitumor effects of this vaccine in these patients.

OUTLINE: This is a pilot study. Patients are stratified according to disease type (acute myeloid leukemia [AML] and myelodysplastic syndromes [MDS] vs non-small cell lung cancer and mesothelioma).

Patients receive vaccine comprising WT-1 vax peptide emulsified in Montanide ISA-51 subcutaneously (SC) once a week during weeks 0, 4, 6, 8, 10, and 12 and sargramostim (GM-CSF) SC twice a week, during weeks 0, 4, 6, 8, 10, and 12, on the day of and 2 days prior to each vaccination. Patients who have an immunologic response and have not had disease progression may continue with up to 6 more vaccinations administered approximately every month.

Blood samples are acquired at baseline, week 8, and week 14. Samples are examined by polymerase chain reaction (PCR) to measure levels of WT-1 and by T-cell proliferative response, delayed-type hypersensitivity against WT-1 peptides, or ELISPOT to measure immune response.

Bone marrow samples are acquired from patients with AML and MDS at baseline and week 14. Samples are examined by PCR to measure levels of WT-1 and by multiparameter flow cytometry to measure residual disease.

PROJECTED ACCRUAL: A total of 20 patients will be accrued for this study.

## Eligibility

Ages Eligible for Study: 18 Years and above, Genders Eligible for Study: Both

#### Criteria

##### DISEASE CHARACTERISTICS:

- Cytologically or histologically confirmed diagnosis of 1 of the following:
- Acute myeloid leukemia, meeting the following criteria:
- Documented Wilms tumor-1 (WT-1)-positive disease demonstrated by WT-1 protein on a pretreatment bone marrow biopsy OR detectable disease with real-time quantitative reverse transcriptase-polymerase chain reaction (RQ-PCR)
- Completed induction chemotherapy, achieved clinical remission, and completed postremission therapy OR achieved clinical remission and have no plans for further postremission chemotherapy ( $\geq 65$  years of age)
- Myelodysplastic syndromes, meeting the following criteria:
- Documented WT-1-positive disease demonstrated by WT-1 protein on a pretreatment bone marrow biopsy OR detectable disease by RQ-PCR
- International Prognostic Scoring System (IPSS) score of  $\geq$  Int-2
- Not a candidate for cytotoxic chemotherapy
- Non-small cell lung cancer, meeting the following criteria:
- Positive tumor staining for WT-1 in  $> 10\%$  of cells
- Stage III or IV disease

- Completed chemotherapy, surgery, and/or radiation treatment
- Mesothelioma, meeting the following criteria:
- Positive tumor staining for WT-1 in > 10% of cells
- Unresectable or relapsed disease
- Chemo-naive or 1 prior chemotherapy regimen
- Malignant pleural mesothelioma or peritoneal mesothelioma allowed
- No leptomeningeal disease
- No CNS involvement

**PATIENT CHARACTERISTICS:**

- Karnofsky performance status 70-100%
- Absolute neutrophil count  $\geq 1,000/\text{mm}^3$
- Platelet count  $> 50,000/\text{mm}^3$  (except for myelodysplastic syndromes where parameter is  $> 20,000/\text{mm}^3$  and not transfusion dependent)
- Bilirubin  $\leq 2.0$  mg/dL
- AST and ALT  $\leq 2.5$  times upper limit of normal
- Creatinine  $\leq 2.0$  mg/dL
- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception
- No active infection requiring systemic antibiotics, antiviral, or antifungal treatments
- No serious unstable medical illness

**PRIOR CONCURRENT THERAPY:**

- See Disease Characteristics
- At least 4 weeks since prior chemotherapy or radiation treatment
- No concurrent systemic corticosteroids

## Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00398138

### New York

Memorial Sloan-Kettering Cancer Center, New York, New York, 10021, United States; Recruiting

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Study chairs or principal investigators

Lee M. Krug, MD, Principal Investigator, Memorial Sloan-Kettering Cancer Center

## More Information

Study ID Numbers: CDR0000513334; MSKCC-06085

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