



Mesothelioma Articles

Antineoplaston Therapy in Treating Patients With Advanced Mesothelioma

This study is currently recruiting patients.

Verified by National Cancer Institute (NCI) September 2006

Sponsored by:	Burzynski Research Institute
Information provided by:	National Cancer Institute (NCI)
ClinicalTrials.gov Identifier:	NCT00003508

Purpose

RATIONALE: Antineoplastons are naturally-occurring substances that may also be made in the laboratory. Antineoplastons may inhibit the growth of cancer cells.

PURPOSE: This phase II trial is studying how well antineoplaston therapy works in treating patients with advanced [mesothelioma](#).

Condition	Intervention	Phase
Advanced Malignant Mesothelioma Recurrent Malignant Mesothelioma	Drug: antineoplaston A10 Drug: antineoplaston AS2-1 Procedure: alternative product therapy Procedure: biological therapy Procedure: biologically based therapies Procedure: cancer prevention intervention Procedure: complementary and alternative therapy Procedure: differentiation therapy	Phase II

MedlinePlus related topics: Cancer; Cancer Alternative Therapies; Mesothelioma

Genetics Home Reference related topics: Cancer

Study Type: Interventional

Study Design: Treatment

Official Title: Phase II Study of Antineoplastons A10 and AS2-1 in Patients With Stage IV Mesothelioma

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

OBJECTIVES:

- Provide treatment with antineoplastons A10 and AS2-1 to patients with stage IV mesothelioma.
- Describe the response to, tolerance to, and side effects of this regimen in these patients.

OUTLINE: Patients receive gradually escalating doses of antineoplaston A10 and antineoplaston AS2-1 IV six times per day until the maximum dose is reached.

Treatment continues for at least 3 months in the absence of disease progression or unacceptable toxicity. After 3 months, patients with stable or responding disease may continue treatment. Patients achieving complete response (CR) continue treatment for at least 8 months beyond CR.

Patients are followed every 2 months for 1 year and then every 3 months for the second year.

PROJECTED ACCRUAL: Approximately 20-40 patients will be accrued for this study.

Eligibility

Ages Eligible for Study: 1 Year and above, Genders Eligible for Study: Both

Criteria

DISEASE CHARACTERISTICS:

- Histologically confirmed stage IV mesothelioma that is unlikely to respond to existing therapy and for which no curative therapy exists
- Evidence of disease by CT scan or MRI

PATIENT CHARACTERISTICS:

Age:

- 1 and over

Performance status:

- Karnofsky 60-100%

Life expectancy:

- At least 2 months

Hematopoietic:

- WBC at least 2,000/mm³
- Platelet count at least 50,000/mm³

Hepatic:

- Bilirubin no greater than 2.5 mg/dL
- SGOT and SGPT no greater than 5 times upper limit of normal
- Hepatic function adequate

Renal:

- Creatinine no greater than 2.5 mg/dL
- No renal insufficiency
- No history of renal conditions that contraindicate high dosages of sodium

Cardiovascular:

- No uncontrolled hypertension
- No history of congestive heart failure
- No cardiovascular conditions that contraindicate high dosages of sodium

Pulmonary:

- No serious lung disease (e.g., chronic obstructive pulmonary disease)

Other:

- Not pregnant or nursing
- Fertile patients must use effective contraception during and for 4 weeks after study participation
- Not at high medical or psychiatric risk
- No nonmalignant systemic disease
- No active infection

PRIOR CONCURRENT THERAPY:

Biologic therapy:

- At least 4 weeks since prior immunotherapy and recovered
- No concurrent immunomodulatory agents

Chemotherapy:

- At least 4 weeks since prior chemotherapy (6 weeks for nitrosoureas) and recovered

Endocrine therapy:

- Concurrent corticosteroids allowed

Radiotherapy:

- At least 8 weeks since prior radiotherapy (or less if multiple tumors) and recovered

Surgery:

- Recovered from prior surgery

Other:

- Prior cytodifferentiating agents allowed
- No prior antineoplastons
- No other concurrent antineoplastic agents

Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00003508

Texas

Burzynski Clinic, Houston, Texas, 77055-6330, United States; Recruiting

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Study chairs or principal investigators

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More Information

Clinical trial summary from the National Cancer Institute's PDQ® database

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Health Authority: United States: Federal Government

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www.MIRG.org