Mesothelioma Articles

Suberoylanilide Hydroxamic Acid (SAHA) Versus Placebo in Advanced Malignant Pleural Mesothelioma

This study is currently recruiting patients.

Verified by Merck April 2007

Sponsored by:	**Merck**
Information provided by:	Merck
ClinicalTrials.gov Identifier:	NCT00128102

Purpose

This is a study to determine the safety, tolerability, and anti-tumor effectiveness of an oral investigational drug, suberoylanilide hydroxamic acid, in the treatment of advanced malignant pleural mesothelioma.

Condition	Intervention	Phase
Mesothelioma Lung Cancer	Drug: MK0683, vorinostat, Suberoylanilide Hydroxamic Acid (SAHA) / Duration of Treatment PD or unacceptable toxicity Drug: Placebo / Duration of Treatment PD or unacceptable toxicity	Phase III

MedlinePlus related topics: Lung Cancer; Mesothelioma

Study Type: Interventional
Study Design: Treatment, Randomized, Double-Blind, Placebo Control, Parallel Assignment, Safety/Efficacy Study

Official Title: A Phase III, Randomized, Double-Blind, Placebo-Controlled Trial of Oral Suberoylanilide Hydroxamic Acid (SAHA) in Patients With Advanced Malignant Pleural Mesothelioma Previously Treated With Systemic Chemotherapy.

Further study details as provided by Merck:
Primary Outcomes: Overall survival and safety/toxicity.
Secondary Outcomes: Overall objective response, response duration, progression-free-survival dyspnea score on LCSS-Meso and Forced Vital Capacity change.
Expected Total Enrollment: 660

Study start: July 2005

Eligibility

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

Criteria

Inclusion Criteria:

- Patient must be 18 years or older with confirmed diagnosis of malignant pleural mesothelioma.
- Patient must have failed prior chemotherapy that included pemetrexed with either cisplatin or carboplatin.
- Patient must have adequate bone marrow, liver and kidney function.
- Patient must be capable of self-care and out of bed for more than 50% of waking hours.
- Patient must have ability to swallow pills.

Exclusion Criteria:

- Patient has been treated with other investigational agent that has similar properties
- Patient has an active infection within 2 weeks of the start of study drug, or had treatment with intravenous antibiotic, antiviral, or antifungal medications within 2 weeks of the start of study drug.
- Patient is pregnant or breast feeding

Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00128102

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More Information

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