Mesothelioma Information & Resource Group

Mesothelioma Articles

Bevacizumab (Avastin) and Erlotinib (Tarceva) in Previously Treated Mesothelioma

This study is currently recruiting patients.

Verified by Dana-Farber Cancer Institute January 2007

Sponsors and Collaborators:	**Dana-Farber Cancer Institute** Massachusetts General Hospital University of Chicago
Information provided by:	Dana-Farber Cancer Institute
ClinicalTrials.gov Identifier:	NCT00137826

Purpose

The purpose of this study is to determine whether the combination of the investigational drugs Avastin and Tarceva are effective in patients with mesothelioma who have previously been treated with chemotherapy.

Condition	Intervention	Phase
Mesothelioma	Drug: Erlotinib (Tarceva, OSI-774) Drug: Bevacizumab (Avastin)	Phase II

MedlinePlus related topics: Mesothelioma

Study Type: Interventional
Study Design: Treatment, Non-Randomized, Open Label, Uncontrolled, Single Group Assignment, Efficacy Study

Official Title: Phase II Study of Bevacizumab (Avastin) and Erlotinib (Tarceva) in Previously Treated Malignant Mesothelioma

Further study details as provided by Dana-Farber Cancer Institute:

Primary Outcomes: To determine the response to the combination of bevacizumab and erlotinib in previously treated malignant mesothelioma
Secondary Outcomes: To determine the time to tumor progression; to determine the duration of response; to determine the median and overall survival of patients; to determine the safety of the drugs administered
Expected Total Enrollment: 37

Study start: February 2004

Each cycle of study treatment lasts 21 days. The patient will take erlotinib by mouth once daily. On day 1 of every cycle, the patient will receive bevacizumab intravenously over a 30-90 minute time period.

CT scan(s), MRI(s) and/or x-ray(s) of the cancer site will be performed every 6 weeks (2 cycles) to assess the extent of the response to treatment.

Bloodwork will be performed before the first dose of erlotinib and bevacizumab at Cycle 1, Cycle 2, Cycle 3, and at the end of treatment.

At the completion of the treatment a physical exam, vital signs, blood tests, urine tests and standard radiologic testing will be performed.

The duration of study depends upon how the patients' mesothelioma responds to treatment as well as how well the patient tolerates the medication.

Eligibility

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

Criteria

Inclusion Criteria:

- Mesothelioma that has been previously treated with at least one chemotherapy regimen
- 18 years of age or older
- Must at least be able to walk and capable of taking care of oneself although unable to carry out work activities
- Four or more weeks since last major surgery
- Four or more weeks since last radiation therapy
- Three or more weeks since last chemotherapy
- Life expectancy of 12 weeks or more
- Blood tests that show kidneys, liver and bone marrow to be working adequately
- Able to comply with study and/or follow-up procedures

Exclusion Criteria:

- Prior exposure to Tarceva (OSI-774, erlotinib), trastuzumab, ZD1839 or C225
- Receiving anticoagulation medication other than low dose Coumadin
- Clinically significant heart disease such as uncontrolled hypertension, previous heart attack within past 12 months, uneven heartbeat, etc.
- History of central nervous system disease such as seizures not controlled with standard medical therapy, brain metastases or history of stroke
- Major surgery within 28 days of screening
- Daily treatment with aspirin or anti-inflammatory medications
- Pregnant or lactating (pertaining to women only)
- Serious or nonhealing wound, ulcer or bone fracture
- Difficulty swallowing
- A disease or disorder that interferes with ability to digest and absorb food
- History of coughing up more than 1/4 teaspoon of blood
- A medical condition that could make it unsafe for patient to participate in this study

Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00137826

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More Information

Dana-Farber Cancer Institute Lowe Thoracic Oncology Program

Publications

Shepherd FA, Rodrigues Pereira J, Ciuleanu T, Tan EH, Hirsh V, Thongprasert S, Campos D, Maoleekoonpiroj S, Smylie M, Martins R, van Kooten M, Dediu M, Findlay B, Tu D, Johnston D, Bezjak A, Clark G, Santabarbara P, Seymour L; National Cancer Institute of Canada Clinical Trials Group. Erlotinib in previously treated non-small-cell lung cancer. N Engl J Med. 2005 Jul 14;353(2):123-32.

Perez-Soler R, Chachoua A, Hammond LA, Rowinsky EK, Huberman M, Karp D, Rigas J, Clark GM, Santabarbara P, Bonomi P. Determinants of tumor response and survival with erlotinib in patients with non--small-cell lung cancer. J Clin Oncol. 2004 Aug 15;22(16):3238-47.

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