Mesothelioma Articles

Combination Chemotherapy With or Without Surgery and Chemoradiotherapy in Treating Patients With Malignant Pleural Mesothelioma

This study is currently recruiting patients.

Verified by National Cancer Institute (NCI) August 2006

Sponsors and Collaborators:	**Case Comprehensive Cancer Center** National Cancer Institute (NCI)
Information provided by:	National Cancer Institute (NCI)
ClinicalTrials.gov Identifier:	NCT00354393

Purpose

RATIONALE: Drugs used in chemotherapy, such as methotrexate, vinorelbine, and cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving chemotherapy before surgery may make the tumor smaller and reduce the amount of normal tissue that needs to be removed. Radiation therapy uses high-energy x-rays to kill tumor cells. Cisplatin may also make tumor cells more sensitive to radiation therapy. Giving chemotherapy and radiation therapy after surgery may kill any tumor cells that remain after surgery.

PURPOSE: This phase II trial is studying how well giving combination chemotherapy with or without surgery and chemoradiotherapy works in treating patients with malignant pleural mesothelioma.

Condition	Intervention	Phase
Localized Malignant Mesothelioma Sarcomatous Mesothelioma Advanced Malignant Mesothelioma Epithelial Mesothelioma	Drug: cisplatin Drug: methotrexate Drug: vinorelbine ditartrate Procedure: adjuvant therapy Procedure: chemotherapy Procedure: conformal radiation therapy Procedure: conventional surgery Procedure: intensity-modulated radiation therapy Procedure: neoadjuvant therapy Procedure: radiation therapy Procedure: radiosensitization Procedure: surgery	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 Induction Combination Chemotherapy Comprising Methotrexate, Vinorelbine Ditartrate, and Cisplatin With or Without Surgery and Adjuvant Chemoradiotherapy in Patients With Malignant Pleural Mesothelioma

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

OBJECTIVES:

Primary

- Assess the response to induction combination chemotherapy comprising methotrexate, vinorelbine ditartrate, and cisplatin in patients with previously untreated malignant pleural mesothelioma.

Secondary

- Assess the tolerability and toxicity of this regimen in these patients.
- Determine relapse-free and overall survival of patients treated with induction combination chemotherapy with or without surgery and hemithoracic radiation.
- Assess the impact of induction combination chemotherapy on operability and surgical success.
- Evaluate the impact of these treatment regimens on quality of life.

OUTLINE:

- Induction chemotherapy: Patients receive MVP chemotherapy comprising cisplatin IV over 30-60 minutes on day 1 and vinorelbine ditartrate IV over 5-10 minutes and methotrexate IV over 5-30 minutes on days 8, 15, and 22. Treatment repeats every 28 days for 2 courses. Patients with unresectable disease may receive up to 2 additional courses of induction chemotherapy. Patients requiring palliative radiotherapy or who have progressive disease are removed from the study. Patients with resectable disease or sarcomatoid histology and T1-3, N1-2 disease with a complete or partial response to induction chemotherapy proceed to surgery.
- Surgery: Patients with extensive disease undergo palliative debulking pleurectomy and decortication and then are taken off study. All other patients undergo a thoracotomy with an extrapleural pneumonectomy and then proceed to chemoradiotherapy.
- Chemoradiotherapy: Beginning 6-10 weeks after surgery, patients undergo 3-dimensional conformal or intensity-modulated radiotherapy once daily, 5 days a week, for 6 weeks. Patients also receive cisplatin IV over 30-60 minutes on days 1 and 22. Patients with responding disease proceed to adjuvant chemotherapy.
- Adjuvant chemotherapy: Patients receive 2 additional courses of MVP chemotherapy as above.

Quality of life is assessed at baseline, after each course of induction chemotherapy, before surgery, and then every 3 months thereafter.

After completion of study therapy, patients are followed every 3 months.

PROJECTED ACCRUAL: A total of 36 patients will be accrued for this study.

Eligibility

Ages Eligible for Study: up to 75 Years, Genders Eligible for Study: Both

Criteria

DISEASE CHARACTERISTICS:

- Histologically confirmed malignant pleural mesothelioma
- Amenable to aggressive surgical resection, if deemed resectable
- Patients with potentially resectable disease must have undergone mediastinoscopy to establish surgical stage

- Resectable disease is defined as any of the following:
- Epithelioid, mixed histology, or histology not otherwise specified with clinical stage I-III (T1-3, N0-2, M0) disease
- Sarcomatoid histology with clinical stage I-III (T1-3, N0) disease
- Intraperitoneal extension, contralateral thoracic extension, or distant metastases are eligible, but considered unresectable
- Disease considered unresectable by any medical reason or if surgery was declined

PATIENT CHARACTERISTICS:

- ECOG performance status 0-1
- WBC ≥ 3,000/mm³
- Platelet count > 100,000/mm³
- Creatinine ≤ 1.7 mg/dL
- Alkaline phosphatase < 2 times normal
- AST < 2 times normal
- Albumin > 3 g/dL
- Bilirubin < 2.0 mg/dL
- Patients must be available for and compliant with adequate long-term follow-up
- Not pregnant
- Negative pregnancy test
- Fertile patients must use effective contraception
- Patients with resectable disease must have adequate pulmonary function to undergo surgery and radiotherapy
- No other active malignancies

PRIOR CONCURRENT THERAPY:

- No prior surgical resection, radiation therapy, chemotherapy, or immunotherapy for this cancer

Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00354393

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More Information

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