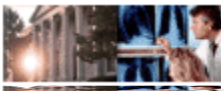

MIRG Mesothelioma Information & Resource Group

Mesothelioma Articles

Pemetrexed Disodium and Either Gemcitabine or Carboplatin in Treating Patients With Advanced Malignant Pleural Mesothelioma

This study is currently recruiting patients.

Verified by National Cancer Institute (NCI) July 2006

Sponsors and Collaborators:	**Eastern Cooperative Oncology Group** National Cancer Institute (NCI) North Central Cancer Treatment Group
Information provided by:	National Cancer Institute (NCI)
ClinicalTrials.gov Identifier:	NCT00101283

Purpose

RATIONALE: Drugs used in chemotherapy, such as pemetrexed disodium, gemcitabine, and carboplatin, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving more than one drug (combination chemotherapy) may kill more tumor cells. It is not yet known whether giving pemetrexed disodium with gemcitabine is more effective than giving pemetrexed disodium with carboplatin in treating malignant pleural mesothelioma.

PURPOSE: This randomized phase II trial is studying pemetrexed disodium and gemcitabine to see how well they work compared to pemetrexed disodium and carboplatin in treating patients with advanced malignant pleural mesothelioma.

Condition	Intervention	Phase
Advanced Malignant Mesothelioma Recurrent Malignant Mesotheliom	Drug: carboplatin Drug: gemcitabine hydrochloride Drug: pemetrexed disodium Procedure: chemotherapy	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 Randomized Study of Pemetrexed Disodium Combined With Either Gemcitabine or Carboplatin in Patients With Advanced Malignant Mesothelioma of the Pleura

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

OBJECTIVES:

Primary

- Compare the response rates in patients with advanced malignant mesothelioma of the pleura treated with pemetrexed disodium combined with either gemcitabine or carboplatin.

Secondary

- Compare the relative toxic effects of these regimens in these patients.
- Compare survival time in patients treated with these regimens.
- Correlate smoking status with outcome in patients treated with these regimens.

OUTLINE: This is a randomized, multicenter study. Patients are randomized to 1 of 2 treatment arms.

- Arm I: Patients receive pemetrexed disodium IV over 10 minutes and carboplatin IV over 30 minutes on day 1.
- Arm II: Patients receive pemetrexed disodium as in arm I and gemcitabine IV over 30 minutes on days 1 and 8.

In both arms, treatment repeats every 21 days for up to 6 courses in the absence of disease progression or unacceptable toxicity.

Beginning approximately 5-10 days before the start of chemotherapy and continuing until approximately 3 weeks after completion of chemotherapy, all patients receive oral folic acid once daily and cyanocobalamin (vitamin B12) intramuscularly every 9 weeks.

Patients are followed every 3 months for 2 years and then every 6 months for 1 year.

PROJECTED ACCRUAL: A total of 32-60 patients (16-30 per treatment arm) will be accrued for this study within 12.8-27.0 months.

Eligibility

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

Criteria

DISEASE CHARACTERISTICS:

- Cytologically confirmed advanced mesothelioma of the pleura
- Measurable disease
- Unmeasurable pleural rinds allowed provided disease is evaluable by mesothelioma response criteria
- The following are not considered measurable disease:
- Pleural effusions
- Positive bone scans
- Not a candidate for curative surgery
- No known or suspected brain metastases

PATIENT CHARACTERISTICS:

Age

- 18 and over

Performance status

- ECOG 0-1

Life expectancy

- Not specified

Hematopoietic

- Absolute neutrophil count ≥ 1,500/mm^3
- Platelet count ≥ 100,000/mm^3

Hepatic

- Bilirubin ≤ 1.5 times upper limit of normal (ULN)
- AST and ALT ≤ 3 times ULN (5 times ULN if liver has tumor involvement)
- Albumin ≥ 2.5 g/dL

Renal

- Creatinine clearance ≥ 45 mL/min OR
- Creatinine ≤ 2.0 g/dL

Other

- Able to take folic acid and cyanocobalamin (vitamin B12)
- Willing and able to take dexamethasone
- Not obviously malnourished
- No weight loss > 10% within the past 6 weeks
- No active infection
- No other serious systemic disorder that would preclude study participation
- No other malignancy within the past 3 years except carcinoma of the cervix or breast, other malignancies, or adequately treated basal cell skin cancer
- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception during and for 3 months after study participation

PRIOR CONCURRENT THERAPY:

Biologic therapy

- No prior intracavitary immunomodulators except for the purpose of pleurodesis

Chemotherapy

- No prior systemic chemotherapy

Endocrine therapy

- Not specified

Radiotherapy

- Prior radiotherapy to the target lesion allowed provided both of the following criteria are met:
- The lesion is clearly progressing after prior radiotherapy
- At least 4 weeks since prior radiotherapy

Surgery

- See Biologic therapy
- More than 2 weeks since prior pleurodesis

Other

- More than 4 weeks since prior investigational agents
- No prior intracavitary cytotoxic drugs except for the purpose of pleurodesis
- No aspirin or other nonsteroidal anti-inflammatory drugs for 2 days before, during, and for 2 days after each administration of pemetrexed disodium (5 days before, during, and 2 days after each administration of pemetrexed disodium for piroxicam, naproxen, diflunisal, or nabumetone)

Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00101283

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More Information

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

Study ID Numbers: CDR0000401795; ECOG-E1B03; NCCTG-E1B03
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Health Authority: United States: Federal Government

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