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Pemetrexed-Carboplatin and Gemcitabine-Vinorelbine in Advanced Breast Cancer

This study is currently recruiting participants.

Verified by Eli Lilly and Company, December 2007

Sponsored by:	Eli Lilly and Company
Information provided by:	Eli Lilly and Company
ClinicalTrials.gov Identifier:	NCT00325234

► Purpose

The primary purpose of this study is to help answer the following research questions:

- whether the chemotherapy combination therapy Pemetrexed- Carboplatin or Gemcitabine- Vinorelbine can help patients with advanced breast cancer to make the tumor smaller or disappear and for how long
- to learn more about the side effects in each chemotherapy combination treatment arm
- to assess how patients with advanced breast cancer report health changes while receiving any of the chemotherapy combination arm

Condition	Intervention	Phase
Breast Cancer	Drug: pemetrexed Drug: carboplatin	Phase II

	Drug: gemcitabine Drug: vinorelbine	
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[Genetics Home Reference](#) related topics: [breast cancer](#)

[MedlinePlus](#) related topics: [Breast Cancer](#)

[ChemIDplus](#) related topics: [Carboplatin](#) [Vinorelbine](#) [Pemetrexed](#)

[U.S. FDA Resources](#)

Study Type: Interventional

Study Design: Treatment, Randomized, Open Label, Active Control, Parallel Assignment, Efficacy Study

Official Title: A Randomized Phase II Study of Two Chemotherapy Regimens, Pemetrexed-Carboplatin, and Gemcitabine-Vinorelbine, in Anthracycline and Taxanes Pretreated Advanced Breast Cancer Patients

Further study details as provided by Eli Lilly and Company:

Primary Outcome Measures:

- Tumor response rate [Time Frame: baseline to time of response] [Designated as safety issue: No]

Secondary Outcome Measures:

- Duration of response [Time Frame: time of response to progressive disease] [Designated as safety issue: No]
- Time to response [Time Frame: baseline to response] [Designated as safety issue: No]
- Time to progressive disease [Time Frame: baseline to measured progressive disease] [Designated as safety issue: No]
- Time to treatment failure [Time Frame: baseline to stopping treatment] [Designated as safety issue: Yes]
- Pharmacology toxicity [Time Frame: every cycle] [Designated as safety issue: Yes]

Estimated Enrollment: 144

Study Start Date: June 2006

Estimated Study Completion Date: October 2009

Estimated Primary Completion Date: October 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions

A: Experimental	Drug: pemetrexed 500 mg/m ² , IV, q 21 days until disease progression or unacceptable toxicity Drug: carboplatin AUC 5, IV, q 21 days until disease progression or unacceptable toxicity
B: Active Comparator	Drug: gemcitabine 1200 mg/m ² , IV, day 1 and day 8 q 21 days until disease progression or unacceptable toxicity Drug: vinorelbine 30 mg/m ² , IV, day 1 and day 8 q 21 days until disease progression or unacceptable toxicity

► Eligibility

Ages Eligible for Study: 18 Years and older

Genders Eligible for Study: Female

Criteria

Inclusion Criteria:

- Females with histologic or cytologic diagnosis of advanced breast cancer. Lesions should not be amenable to surgery or radiation of curative intent.
- Performance status of 0 to 2 on the ECOG performance status schedule.
- One prior chemotherapy containing anthracyclines as (neo)adjuvant or palliative 1st-line treatment.
- One prior chemotherapy containing taxanes as (neo)adjuvant or palliative 1st-line treatment.
- Prior radiation therapy is allowed to less than 25% of the bone marrow. Patients must have recovered from the toxic effects of the treatment prior to study enrollment (except for alopecia). Prior radiotherapy must be completed 30 days before study entry. Lesions that have been radiated cannot be included as sites of measurable disease unless clear tumor progression has been documented in these lesions since the end of radiation therapy.
- At least one uni-dimensionally measurable lesion meeting Response Evaluation Criteria in Solid Tumors. Positron emission tomography [PET] scans and ultrasounds may not be used
- Antitumoral hormonal treatment must be discontinued prior to enrollment.
- Estimated life expectancy of at least 3 months.
- Patient compliance and geographic proximity that allow adequate follow-up.
- Adequate organ function

- Female patients of childbearing potential must test negative for pregnancy within 7 days of enrollment based on a urine and/or serum pregnancy test and agree to use a reliable method of birth control during and for 6 months following the last dose of study drug.
- Patients must sign an informed consent document.
- Female patients at least 18 years of age.

Exclusion Criteria:

- Have received treatment within the last 30 days with a drug that has not received regulatory approval for any indication at the time of study entry.
- Have previously completed or withdrawn from this study or any other study investigating Pemetrexed, Gemcitabine, Carboplatin or Vinorelbine
- Have received more than one line of chemotherapy in MBC. Patients having received more than one combination of A plus T.
- Are pregnant or breast-feeding.
- Have serious concomitant systemic disorders (e.g., active infection) that, in the opinion of the investigator, would compromise the safety of the patient or compromise the patient's ability to complete the study.
- Have a prior malignancy other than breast cancer, carcinoma in situ of the cervix, or nonmelanoma skin cancer, unless that prior malignancy was diagnosed and definitively treated at least 5 years previously with no subsequent evidence of recurrence.
- Are unable to interrupt aspirin or other nonsteroidal anti-inflammatory agents for a 5-day period (8-day period for long-acting agents such as piroxicam), unless the Creatinine Clearance is greater than or equal to 80 ml/min.
- Have central nervous system (CNS) metastases.
- Have clinically relevant (by physical exam) third-space fluid collections (for example, ascites or pleural effusions) that cannot be controlled by drainage or other procedures prior to study entry.
- Are unable or unwilling to take folic acid, vitamin B12 supplementation, or dexamethasone.
- Concurrent administration of any other antitumor therapy.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00325234

Contacts

Contact: There may be multiple sites in this clinical trial. 1-877-CTLILLY (1-877-285-4559) or 1-317-615-4559

Locations

Germany

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9
Berlin, Germany, 13125

Contact: Eli Lilly

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9
Essen, Germany, 45131

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Guetersloh, Germany, 33332

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Hamburg, Germany, 22081

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Stuttgart, Germany, 70190

Contact: Eli Lilly

Israel

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Jerusalem, Israel, 91120

Contact: Eli Lilly

For additional information regarding investigative sites for this trial, contact 1-877-CTLILLY (1-877-285-4559, 1-317-615-4559) Mon - Fri from 9
Rehovot, Israel, 76100

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Contact: Eli Lilly

Italy

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Bergamo, Italy, 24128

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Bologna, Italy, 40139

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Campobasso, Italy, 86100

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San Giovanni Rotondo, Italy, 71013

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Meldola, Italy, 47014

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Rome, Italy, 00168

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Livorno, Italy, 57128

Contact: Eli Lilly

South Africa

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Durban, South Africa, 4067

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Morningside, South Africa, 2199

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Pretoria, South Africa, 0081

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Spain

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Barcelona, Spain, 08036

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Madrid, Spain, 28040

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Lleida, Spain, 25198

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Girona, Spain, 17007

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Valencia, Spain, 46010

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Switzerland

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Turkey

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Kayseri, **Turkey**, 38039

Contact: Eli Lilly

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Besevler/Ankara, **Turkey**, 06500

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Izmir, **Turkey**, 35100

Contact: Eli Lilly

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Istanbul, **Turkey**, 34390

Contact: Eli Lilly

Sponsors and Collaborators

Eli Lilly and Company

Investigators

Study Director: Call 1-877-CTLILLY (1-877-285-4559) or 1-317-615-4559 Mon- Fri 9 AM - 5 PM Eastern time (UTC/GMT - 5 hours, EST) E

▶ More Information

[Lilly Clinical Trial Registry](#) 

Responsible Party: Eli Lilly (Chief Medical Officer)

Study ID Numbers: 10826, H3E-EW-S098

First Received: May 10, 2006

Last Updated: December 21, 2007

ClinicalTrials.gov Identifier: [NCT00325234](#)

Health Authority: Germany: Federal Institute for Drugs and Medical Devices; Turkey: Ministry of Health; Israel: Israeli Health Ministry Pharmaceutical Administration; Italy: Ministry of Health; Spain: Spanish Agency of Medicines; Switzerland: Swissmedic

Study placed in the following topic categories:

Folic Acid

Pemetrexed

Vinorelbine

Skin Diseases

Connective Tissue Diseases

Breast Neoplasms

Carboplatin

Gemcitabine

Taxane

Breast Diseases

Additional relevant MeSH terms:

Skin and Connective Tissue Diseases

Antimetabolites

Anti-Infective Agents

Antimetabolites, Antineoplastic

Immunologic Factors

Antineoplastic Agents

Physiological Effects of Drugs

Enzyme Inhibitors

Folic Acid Antagonists

Antiviral Agents

Immunosuppressive Agents

Molecular Mechanisms of Action

Pharmacologic Actions

Neoplasms

Neoplasms by Site

Radiation-Sensitizing Agents

Therapeutic Uses

Antineoplastic Agents, Phytogetic

ClinicalTrials.gov processed this record on January 09, 2008

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