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THE CLINICAL CANCER LETTER

Cancer research news for clinicians

Chemotherapy Patients Can Benefit From Heart Failure Treatment, Study Finds

Researchers at The University of Texas M. D. Anderson Cancer Center have found that cancer patients who develop heart failure as a result of chemotherapy treatment can be effectively treated, with the condition potentially reversed, when standard medicated therapy for heart failure is used.

The findings were presented at the annual meeting of the Heart Failure Society of America in Boca Raton, Fla., by Jean-Bernard Durand, assistant professor in the Department of Cardiology and director of Cardiomyopathy Service at M. D. Anderson.

(Continued to page 2)

Clinical Trials:

Zometa Reduced Bone Complications In Patients With Prostate Cancer Bone Mets

Zometa (zoledronic acid for injection) significantly reduced the number of bone-related complications by 25% relative to placebo in patients with bone metastases from advanced prostate cancer, according to a study in the Journal of the National Cancer Institute.

In the study, Zometa was infused at a dose of 4 mg given over 15 minutes.

"Bone metastases and their complications can be catastrophic for patients with advanced cancer," said Fred Saad, Uro-Oncology Clinic, Centre Hospitalier de l'Université de Montréal, Hôpital Notre-Dame, Montreal, Canada. "This study shows that Zometa significantly reduces and delays these complications–including pathological fractures, spinal cord compression and the need for radiation. This represents a major advance in the treatment of advanced prostate cancer."

The results were from a randomized, phase III double-blind, placebo-controlled study of 643 prostate cancer patients who progressed despite hormonal therapy with at least one bone metastasis.

The analysis was based on evaluating Zometa 4 mg (in 100 ml of solution) compared to placebo at an infusion rate of 15 minutes, given every three weeks for 15 months.

The data demonstrated that patients taking Zometa 4 mg experienced 25% fewer SREs compared to those patients taking placebo (Zometa 33% vs. placebo 44%, p=0.021). The 15-month data also demonstrated that Zometa significantly delayed median time to first skeletal related

(Continued to page 2)

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ACE Inhibitors, Beta Blockers Effective In Cancer Patients

(Continued from page 1)

The retrospective studies showed that patients treated with ACE-inhibitors and the beta-blocking agent, carvedilol, had significant improvements in two measures of heart failure: ejection fraction and New York Heart Association functional class. Previously, many cancer patients endured the invasive insertion of cardiac devices or full heart transplants in an effort to treat heart failure resulting from chemotherapy treatment.

The research has not been traditionally studied in cancer patients, and is the first to evaluate the treatment of heart failure using standard medication therapy in patients undergoing chemotherapy.

"Until now, heart failure was thought to be irreversible in chemotherapy patients with many cardiologists advising patients who develop the condition to reduce their chemotherapy regimens," said Durand, lead investigator for the study. "This data suggests that patients can continue their chemotherapy regimens, yet effectively reduce their risk of worsening heart failure and the eventual need for heart transplantation."

Durand presented two retrospective studies evaluating the treatment of heart failure in chemotherapy patients. In one study, investigators reviewed the medical records of 15 cancer inpatients with class IV heart failure evaluated in M.D. Anderson's cardiomyopathy clinic. Cancer diagnosis, ejection fraction, recorded symptoms and hemodynamic data were examined before and after the use of intravenous inotropic agents, beta-blocking agents, ACE inhibitors and diuretics. Fourteen of the 15 patients achieved significant recovery of cardiac function and improvement in NYHA functional class following treatment and 13 patients were successfully discharged on a regimen of ACE inhibitors in combination with carvedilol.

In a second study, Durand and investigators reviewed the medical records from 16 cancer outpatients with mild to severe heart failure, diagnosed at initial evaluation in M. D. Anderson's cardiomyopathy clinic.

All 16 patients received standard combination therapy for heart failure, which included ACE inhibitors, diuretics and the beta-blocking agent carvedilol, unless unable to tolerate therapy. Ten patients had baseline left ventricular ejection fraction of less than 40 percent and six patients had LVEF of greater than 40 percent.

Results showed that carvedilol treatment alone yielded a mean increase in ejection fraction units in both groups of patients, 22 percent and 15 percent, respectively. Carvedilol in combination with an ACE inhibitor yielded a 25 percent increase in ejection fraction in patients with LVEF less than 40 percent and a 16 percent increase in patients with LVEF more than 40 percent.

"The data demonstrate that chemotherapy-induced heart failure may be reversible with standard medicated therapy for the condition," Durand said. "The implications of this research could lead to better chemotherapy regimens for patients without concern for developing a potentially fatal condition as a result of their cancer treatment."

M. D. Anderson researchers have proposed conducting a broader-scaled study in the near future to further analyze these observations.

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Clinical Trials:

Zometa Found To Reduce Complications From Bone Mets

(Continued from page 1)

event by over 3 months (p=0.011). Initially, a third arm of the study evaluated an 8 mg dose of Zometa; however, that dose offered no efficacy advantage compared to the recommended dose (4 mg/15 minute

infusion), but was associated with a higher incidence of adverse events, including increased serum creatinine levels. Therefore, dosing on this arm was changed to 4 mg and was not included in this efficacy analysis.

Zometa is indicated to treat multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy.

In prostate cancer, patients should have progressed after treatment with at least one hormonal therapy. These solid tumors studied include prostate cancer, breast cancer, and other solid tumor types including renal, colorectal and lung.

Zometa is also indicated for the treatment of hypercalcemia of malignancy. Zometa and other bisphosphonates have been associated with reports of renal insufficiency. Patients should have serum creatinine assessed prior to receiving each dose of Zometa. Caution is advised when Zometa is used in aspirin sensitive patients or with aminoglycosides, loop diuretics, and other potentially nephrotoxic drugs.

In the clinical studies, patients with serum creatinine >3.0 mg/dL were excluded. In clinical trials in patients with bone metastases, Zometa had a safety profile similar to other intravenous bisphosphonates. The most commonly reported adverse events in bone metastases clinical trials, regardless of causality with Zometa, included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anemia, weakness, cough, dyspnea and edema. Zometa should not be used during pregnancy.

High-Starch Diet May Raise Risk Of Pancreatic Cancer

A diet high in starchy foods such as potatoes, rice and white bread may increase the risk of pancreatic cancer in women who are overweight and sedentary, according to a study by Dana-Farber Cancer Institute, Brigham and Women's Hospital, and Harvard School of Public Health.

Published in the Sept. 4 issue of the Journal of the National Cancer Institute, the study suggests that excess insulin can promote the development of pancreatic cancer.

"Our findings add to the growing body of evidence that suggests that insulin may have a role in the development of pancreatic cancer," said senior author Charles Fuchs, of Dana-Farber. "Further research is needed, however, to track the connection in more detail."

Earlier laboratory studies have demonstrated that insulin encourages the growth of pancreatic cancer cells. Other studies have shown that people who are obese, physically inactive, or have adult-onset diabetes mellitus tend to be "insulin resistant," causing them to produce larger-than-normal amounts of insulin to compensate and putting themselves at greater risk for pancreatic cancer. The new study explored whether women whose diets are heavy in foods that increase insulin production are likewise at elevated risk for pancreatic cancer.

"Historically, cigarette smoking had been the only proven risk factor for developing pancreatic cancer," said the study's lead author, Dominique Michaud, of the National Cancer Institute, who initiated the research while at Harvard School of Public Health.

Data for the study came from the Nurses' Health Study. The researchers reviewed the dietary records of nearly 89,000 nurses to measure their intake of sucrose, fructose, and carbohydrates.

The researchers also calculated the amount of glucose-stimulating foods every study participant consumed. Each type of food increases glucose levels by a different amount. The ability of carbohydrate-containing foods to boost glucose, and thereby insulin, levels is known as the "glycemic index." Starchy foods such as potatoes, white rice, and white or rye bread have high glycemic indexes.

The researchers found that women who were significantly overweight and physically inactive (and whose levels of glucose and insulin were therefore already above normal) were more than two-and-a-half times more likely to develop pancreatic cancer if they had a high glycemic load than if they had a low glycemic load. A high glycemic load did not increase pancreatic cancer risk among women who were lean and physically fit.

An analysis of pancreatic cancer rates in all of the women in the study showed that women who had high glycemic loads were 53 percent more likely to develop pancreatic cancer than were those with low loads. Women who consumed large amounts of fructose had a 57 percent greater risk of pancreatic cancer. Neither of these trends reached the level of statistical significance due to the limited number of cancer cases in each category.

"The take-home message for women who are overweight and sedentary is that a diet high in starchy

foods may increase their risk of pancreatic cancer," said Fuchs. "Substituting less starchy vegetables such as broccoli for potatoes and rice and snacking on fruit are some simple steps that they can take to reduce this potentially serious health risk."

NCI Grant Boosts UCLA Bladder Cancer Project

University of California, Los Angeles, Jonsson Cancer Center has begun a program to prevent smoking-related bladder cancer.

As part of the program, researchers will develop biomarker tests to help predict who will get bladder cancer, discover the molecular profile of the disease to identify those most at risk, conduct a clinical trial testing green tea extract and the experimental drug Iressa as prevention agents and create a tumor bank to aid in scientific research.

The five-year effort is funded through a $5.9 million cancer prevention grant from the National Cancer Institute to the cancer center, the department of urology and the division of urologic oncology. This is the largest prevention study in the U.S. to focus on bladder cancer in current and former smokers, UCLA researchers said.

While it is widely known that smoking causes lung cancer, tobacco use also is a major risk factor for bladder cancer, said Arie Belldegrun, chief of the division of urologic oncology, professor of urology, and principal investigator for the project.

"We will study innovative approaches to reduce the risk of bladder cancer," Belldegrun said. "And while we'll study prevention in patients who have already had bladder cancer, our goal is to develop effective prevention strategies for people who may be at risk but who do not yet have bladder cancer."

Most bladder cancer cases are smoking-related, said Robert Figlin, a Jonsson Cancer Center researcher, a professor of hematology/oncology and urology and co-principal investigator for the study. Cigarette smokers are two to three times more likely than nonsmokers to get bladder cancer.

"What we're doing is looking for things that tell us why some people get this disease and others don't," Figlin said. "We want to decrease bladder cancer occurrence and develop molecular profiles that tell us who is most at risk."

The $5.9 million grant is part of the NCI's chemoprevention program. The Jonsson Cancer Center program will feature four angles of attack, bringing together physicians and scientists from different disciplines, including medicine, urology, epidemiology, biomathematics, biostatistics, pathology and surgery. The program includes:

—A clinical trial for 270 current and former smokers who have already had bladder cancer. The study, led by Allan Pantuck, an assistant professor of urology, will investigate the effectiveness of two compounds in preventing or delaying recurrence of the cancer and will divide volunteers into three arms. One group will receive green tea extract, which has been shown in UCLA laboratories to reduce the growth of bladder cancer tumors both in animal models and in humans. The second group will receive an experimental drug called Iressa, an epidermal growth factor receptor inhibitor that also is being studied in lung and prostate cancers. The third group will receive a placebo.

—Development of a set of biomarkers for bladder cancer that can be used to predict who is likely to develop the disease. Such tests, to be developed by Zuo-Feng Zhang and Jian Yu Rao, could work similarly to the PSA test for prostate cancer.

—With Aarno Palotie of the UCLA Department of Human Genetics, discover a molecular profile of bladder cancer that will help determine susceptibility to the disease. Researchers will seek to uncover what specific genetic mutations and other abnormalities may put people at risk for bladder cancer, such as the BRCA1 and 2 genes do for breast cancer.

—Create a bladder cancer tumor bank for use by UCLA scientists from various medical and research disciplines for development of better prevention, detection and treatment methods for bladder cancer.

Sales of Smoking Cessation Aids Increase, Effectiveness Drops

Nicotine replacement therapies such as the nicotine patch and nicotine gum are no longer effective in helping smokers quit for the long term, according to researchers at the University of California, San Diego School of Medicine.

Over-the-counter availability of these products starting in mid-1996 was the turning point in effectiveness of these products, the researchers said in the Sept. 11 issue of the Journal of the American Medical Association.

At the same time, the number of people trying to quit has gone up dramatically, as has the use of

nicotine replacement therapies (NRTs). More than a third of the most recent NRT users are considered light smokers—those who smoke fewer than 15 cigarettes a day—a group for whom these products are known to be ineffective.

"Since becoming available without prescription in mid-1996, these products have been heavily promoted to the public," said the report's co-author John Pierce, director of the Cancer Prevention and Control Program at the Rebecca and John Moores UCSD Cancer Center. "Unfortunately, advertising does not distinguish between light smokers and those in the medium-to-heavy smoking category."

This new information was compiled from the California Tobacco Surveys, large population surveys undertaken annually since 1990. Researchers focused on the 1992, 1996 and 1999 surveys. During those surveys, interviews were completed on more than 15,000 adult smokers statewide. Among other things, respondents were asked about whether they had in the past year quit intentionally for a day or longer (the standard research definition of a meaningful quit attempt), if they had used a pharmaceutical aid or had other assistance for their last quit attempt, and how long they were off cigarettes the last time they tried.

Over the seven-year span of the surveys in the study (1992-1999), the percentage of smokers trying to quit increased by more than 60 percent (from 38.1 percent to 61.5 percent). At the same time, NRT use increased more than threefold; there were an estimated 116,209 smokers in 1992 who used NRT, 337,142 in 1996, and 423,290 in 1999.

Of the additional smokers using NRT in 1999 compared to 1996, when these products became available over the counter, 37 percent were from the lighter smoking group.

Analysis of the duration of smoking abstinence in each of the study years indicated a significant effect for NRT use. However, in contrast to 1992 and 1996, the effect in 1999 was only short term; after about three months, the effect is about the same as for those who used no aids.

The researchers hypothesize that this shift happened in large part because of the context within which NRTs were available, and the nature of the products themselves.

"When physicians prescribed these products, they likely discussed their proper use and only prescribed them for appropriate users, the moderate-to-heavy smokers," said co-author Elizabeth Gilpin, M.S., of the Cancer Prevention and Control Program at the Moores UCSD Cancer Center. "Also, the products are designed to help with the cravings associated with smoking, but not the behavioral aspects."

The researchers write that this study "highlights the need for more research nationwide concerning the barriers to more appropriate use of NRT," and they suggest that NRTs should be used in combination with other types of smoking-cessation assistance, such as behavioral counseling.

This work was supported by a grant from the University of California Tobacco Related Disease Research Program.

Smokers' Quitlines Work, California Study Finds

Phone-based smoking cessation programs, called quitlines, are effective in helping smokers quit, according to a study by researchers at the University of California, San Diego.

In 1990, UCSD Cancer Center researchers started a clinical trial on telephone counseling for smoking cessation. The results were so encouraging that in 1992 the California Department of Health Services decided to make it a statewide service. The California Smokers' Helpline was the first statewide quitline funded by a state health department.

Today, 33 states in the U.S. have established similar quitlines. Many large managed care organizations have also set up quitlines to help their members. U.S. Public Health Service Clinical Guidelines (2000) recommend the use of quitlines, following extensive review of the clinical trials on telephone counseling.

"Positive results from clinical trials got people excited about starting new quitlines. And some of the early quitlines have done a good job reaching large number of smokers, in particular underserved populations," said the study's lead author, Shu-Hong Zhu, director of the California Smokers' Helpline and a member of the Rebecca and John Moores UCSD Cancer Center. "But it's important to know whether real-world quitline services are able to maintain the effectiveness found in clinical trials, especially since there's a significant and growing public investment in this type of service."

To test whether the quitlines still work, Zhu and colleagues developed a study in which they embedded a randomized control group into the normal operations

of the quitline. The randomization procedure did not affect callers' ability to receive treatment.

The study recruited 3,282 participants, who were randomly assigned to a treatment or control group. All participants received a packet of self-help materials. All were told counseling was available if they called back after receiving the materials. Those in the treatment group were assigned to receive up to seven counseling sessions, and those in the control group also received counseling if they called back for it after randomization. Those in the control group who did not call back remained as self-help subjects.

After factoring out the control subgroup that received counseling and the corresponding treatment subgroup, the researchers found that counseling approximately doubled abstinence rates at 1, 3, 6 and 12 months.

"Quitting smoking is a difficult thing to do," said Zhu, a UCSD associate professor of Family and Preventive Medicine. "The reality is that even with a successful program's help, many smokers relapse within a year. Still, we've shown there's a significantly higher probability of long-term success for people who go through a quitline program than for those who don't."

The California Smokers' Helpline is an ongoing statewide quitline operated by UCSD that provides free cessation services to state residents. Programs are available for teens and adults, in six languages. The service receives calls from more than 55,000 tobacco users per year. Over a third of Helpline callers are from ethnic minority backgrounds.

This research is reported in the October 3 issue of the New England Journal of Medicine. The work was supported by a grant from the California Department of Health Services.

PSA Level Predicts Survival For Prostate Cancer

The level of prostate-specific antigen in the blood of prostate cancer patients five years after radiation treatment can help predict their disease-free survival for the next several years, according to the October 2002 issue of the International Journal of Radiation Oncology, Biology and Physics.

Patients who maintain low five-year PSA levels have a low probability of relapse at 10 years and beyond. The study identified 328 men treated with external beam radiation therapy to the prostate who were biochemically disease-free five years after treatment. The median follow-up was 7.4 years. The patients were divided into four groups according to their PSA values five years after treatment: PSA less than or equal to 0.5, 0.5 to 1.0, 1.0 to 2.0 and 2.0 to 4.0 ng/mL. PSA progression-free rates were calculated in each subgroup at 10 years after treatment.

The PSA progression-free survival rate was 87 percent, 79 percent and 67 percent, respectively, 8, 10 and 13 years after treatment in patients biochemically free of disease five years after treatment. The progression-free rates at 10 years after treatment according to the PSA level at five years was 92 percent for PSA less than or equal to 0.5 ng/mL, 71 percent for PSA 0.5 to 1.0 ng/mL, 78 percent for PSA 1.0 to 2.0 ng/mL and 56 percent for PSA 2.0 to 4.0 ng/mL. The lower the PSA level at five years, the more durable the probability of maintained biochemical disease-free survival.

Researchers concluded that when PSA levels remain low (less than 2 ng/mL) five years after external beam radiation therapy, the great majority of patients will be biochemically disease-free at 10 years. The hazard rates of biochemical progression in the 6 to 10 years after treatment are low and are comparable to rates seen when prostatectomy (surgical removal of the prostate) is the chosen treatment modality.

"This study reinforces the fact that radiation therapy should be used to achieve low PSA levels early in treatment, and those low levels should be maintained to five years and beyond," said Anthony Zietman, of the Department of Radiation Oncology at Massachusetts General Hospital and co-author of the study. "If this can be achieved, the long-term outlook for prostate cancer patients treated with radiation therapy will be good."

ASCO, ASH Issue Guidelines On Use Of Epo For Anemia

The American Society of Clinical Oncology and the American Society of Hematology have reviewed the latest research and developed evidence-based clinical guidelines about the use of epoetin (recombinant hematopoietic growth factor erythropoietin) for the treatment of cancer-related anemia.

The guidelines recommend the use of epoetin for patients with chemotherapy-associated anemia with a hemoglobin level less than 10g/dL. For patients

whose blood-cell count is between 10 and 12 g/dL, doctors should conduct an in-depth evaluation and treat with epoetin on an individual basis based on clinical judgment.

One randomized controlled trial supports the use of epoetin for patients with anemia associated with low-risk myelodysplasia not receiving chemotherapy. There are not, however, any published high-quality studies that support the use of epoetin in other hematologic malignancies for patients not receiving chemotherapy. Dosage and treatment schedules are detailed in the guidelines.

"The guidelines present a distillation of the best available research evidence that supports use of epoetin as well as recommendations for optimal use," said J. Douglas Rizzo, lead author of the practice guideline and assistant scientific director of the International Bone Marrow Transplant Registry at the Medical College of Wisconsin.

The guidelines are available at www.jco.org and at www.bloodjournal.org. The guidelines also were published in the Oct. 1 issues of the Journal of Clinical Oncology, and Blood.

FDA Approves Kytril For Post-Operative Nausea

The U.S. Food and Drug Administration granted approval of Kytril Injection (granisetron hydrochloride, Roche) for both the prevention and treatment of post-operative nausea and vomiting (PONV).

When used for prevention, Kytril is given just before or during surgery to prevent PONV from occurring. In the case of treatment, Kytril is given to a patient who experiences PONV after surgery.

Kytril Injection was evaluated in two randomized, double blind, placebo-controlled studies in patients who underwent gynecological surgery or cholecystectomy and received general anesthesia.

In one study, patients between the ages of 18 and 88 received a single intravenous dose of Kytril Injection (0.1, 1 or 3 mg) or placebo five minutes before induction of anesthesia.

In another study, patients between the ages of 21 and 64 received a single intravenous dose of Kytril Injection (1 or 3 mg) or placebo immediately before the reversal of anesthesia.

In both studies, Kytril Injection (1 mg) was significantly more effective ($p<0.001$) than placebo in preventing postoperative nausea and vomiting.

Kytril Injection was evaluated in two randomized, double blind, placebo-controlled studies of adult surgical patients who received general anesthesia and no prophylactic antiemetic treatment, and who experienced nausea and vomiting within four hours after surgery. In one study, patients between the ages of 18 and 86 received a single intravenous dose of Kytril Injection (0.1mg, 1mg or 3 mg) or placebo after experiencing postoperative vomiting or severe nausea.

This study showed that Kytril Injection given at 0.1mg, 1mg and 3 mg doses were significantly more effective ($p<0.001$) than placebo in preventing further episodes of nausea and vomiting. This study demonstrated efficacy at both time intervals of 0 to 6 hours and 0 to 24 hours for the treatment of PONV.

The recommended dose of Kytril for prevention and treatment of post operative nausea and vomiting is 1 mg. The most common adverse events reported in the postoperative nausea and vomiting trials included pain, headache, and fever.

The FDA first approved Kytril injection in December 1993 for chemotherapy-induced nausea and vomiting. Kytril oral tablets were approved in July 1999, for use in radiation therapy-induced nausea and vomiting.

Cancer Clinical Trials Approved By NCI Last Month Are Listed

The National Cancer Institute's Cancer Therapy Evaluation Program Approved the following clinical research studies last month. For further information about a study, contact the principal investigator listed.

Phase I

Phase I Study of the Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor, OSI-774, in Combination with Docetaxel and Radiation in Locally Advanced Squamous Cell Cancer of the Head and Neck. Case Western Reserve University, protocol 5389, Remick, Scot, phone 216-8449-5412.

Phase I Study of MEDI-522 in Patients with Advanced Solid Tumors. Wayne State University, protocol 5496, LoRusso, Patricia, phone 313-745-8860.

Phase I Study of 5-aza-2'-deoxycytidine as a Biologic Modifier of Retinoid Responsive Genes in Patients with High-Risk Myelodysplastic Syndromes and Relapsed Acute Myelogenous Leukemia (de-novo, relapsed or secondary). Princess Margaret Margaret Hospital Phase 2 Consortium, protocol

5591, Minden, Mark, phone 416-946-2015.

Phase I Study of STI 571 in Combination with Cisplatin/ Irinotecan in Patients with Extensive Stage Small Cell Lung Cancer. Princess Margaret Margaret Hospital Phase 2 Consortium, protocol 5684, Vincent, Mark, phone 519-685-8640.

A Phase I Study of PS-341 in Combination with Gemcitabine and Carboplatin in Selected Stage IIIB or IV Non-Small Cell Lung Cancer. City of Hope Medical Center, protocol 5856, Davies, Angela, phone 916-734-3772.

Pilot Study to Assess the Immunologic Response to Booster Vaccination with a Modified gp100 Melanoma Peptide Vaccine in Previously Vaccinated HLA-A2.1 + Patients with Melanoma. Providence Portland Medical Center, protocol 5925, Urba, Walter, phone 503-215-6259.

Phase II

Multi-institutional, Open-Label, Phase II Study of Doxorubicin and Bevacizumab for Patients With Advanced or Metastatic Soft-Tissue Sarcoma. Memorial Sloan-Kettering Cancer Center, protocol 2270, Maki, Robert, phone 212-639-5720.

Phase II Pilot Study of Clinical Activity and Proteomic Pathway Profiling of the EGFR Inhibitor ZD1839 (Iressa [R]; Getifinib) in Patients with Epithelial Ovarian Cancer or Cervical Cancer. NCI, Medicine Branch, protocol 5561, Kohn, Elise, phone 301-402-2726.

Phase II Study of Oxaliplatin in Hepatocellular Cancer. City of Hope Medical Center, protocol 5589, Yen, Yun, phone 626-359-8111, ext 2691.

Randomized Phase II Study of Gemcitabine Plus Radiotherapy vs. Gemcitabine, 5-Fluorouracil and Cisplatin Followed by Radiotherapy and Advanced, Potentially Resectable Pancreatic Adenocarcinoma. Eastern Cooperative Oncology Group, protocol E1200, Hoffman, John, phone 215-728-3518.

Phase II Study of Low Dose Peginterferon Alfa-2b in Patients with Metastatic Melanoma Over-Expressing Basic Fibroblast Growth Factor. Eastern Cooperative Oncology Group, protocol E2602, Go, Ronald, phone 608-782-7300.

Phase II Trial of STI571 in Patients with Relapsed Small Cell Lung Cancer. North Central Cancer Treatment Group, Adjei, Alex, phone 507-538-0548.

Phase II Randomized Trial for Patients with Muscle-Invading Bladder Cancer Comparing Transurethral Surgery and BID Irradiation Plus Either Taxol and Cisplatin or 5-Fluorouracil and Cisplatin Followed by Selective Bladder Preservation and Gemcitabine/Paclitaxel/Cisplatin Adjuvant Chemotherapy. Radiation Therapy Oncology Group, protocol RTOG-0233, Zietman, Anthony, phone 617-726-8150.

Protocol For Assessment of Capecitabine for Advanced Colorectal Cancer in Patients Aged 70 Years and Older (and in a Cohort of Patients Younger Than 60 Years). Southwest Oncology Group, protocol S0030, Lenz, Heinz-Josef, phone 323-865-3955.

Phase III

Health-Related Quality of Life in Patients With Low Risk, Localized Prostate Cancer Randomized to Radical Prostatectomy or Brachytherapy. American College of Surgeons Oncology Trials, protocol ACOSOG-Z0071, Sandra, Martin, phone 734-763-3564.

Phase III Trial in Adult Acute Myeloid Leukemia: Daunorubicin Dose-Intensification and Gemtuzumab-Ozogamicin Consolidation Therapy Prior to Autologous Stem Cell Transplantation. Eastern Cooperative Oncology Group, protocol E1900, Fernandez, Hugo, phone 305-243-4962.

Phase III Prospective Randomized, Double-Blind, Placebo-Controlled Trial of the Epidermal Growth Factor Receptor Antagonist, ZD 1839 (Iressa)in Completely Resected Stage IB, II and IIIA Non-Small Cell Lung Cancer. NCI, Canada, protocol NCIC-BR.19, Goss, Glennwood, phone 613-737-7700.

Other

The CALGB Lung Cancer Tissue Bank. Cancer and Leukemia Group B, protocol CALGB-140202, Sugarbaker, David, phone 617-732-5004.

Pilot Study Of Sequential Vaccinations With Recombinant Vaccinia-CEA (6D)-TRICOM, and Recombinant Fowlpox-CEA (6D) TRICOM (B7.1/ ICAM-1/LFA-3) with Sargramostim(GM-CSF), in Conjunction with Standard Adjuvant Chemotherapy in High Risk Breast Cancer Patients Status Post Surgery with 4+ or More Lymph Nodes and CEA Expressing Tumors. NCI, Medicine Branch, protocol 5191, Arlen, Philip, phone 301-96-0629.

Intensive Induction Therapy for Children with Acute Lymphoblasic Leukemia who Experience a Bone Marrow Relapse. Children's Oncology Group, protocol Pilot AALL01P2, Raetz, Elizabeth, phone 801-588-2680.