

THE CLINICAL CANCER LETTER

Cancer research news for clinicians

Prostate Cancer:

Immune System Booster Shown Safe For Prostate Cancer; Fewer Side Effects

New research indicates that giving patients a continuous low dose of an immune system booster, a method known as metronomic dosing, as part of a therapeutic prostate cancer vaccine strategy is safe and produces similar immune responses and fewer side effects than the more common dosing method, which is not well tolerated by many patients.

This study, led by researchers at the National Cancer Institute was published in the Aug. 15 issue of *Clinical Cancer Research*.

The vaccine used in this study is designed to stimulate an immune
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Cancer Screening:

Men Over Age 75 Shouldn't Be Screened For Prostate Cancer, Task Force Says

Men age 75 and older should not be screened for prostate cancer, and younger men should discuss the benefits and harms of the prostate-specific antigen test with their clinicians before being tested, according to a new recommendation from the U.S. Preventive Services Task Force.

The recommendation and accompanying evidence summary appear in the Aug. 5 issue of the *Annals of Internal Medicine*.

The Task Force found evidence that screening for prostate cancer provided few health benefits but led to substantial physical harms and some psychological harms in men age 75 and older. In men younger than 75, the Task Force concluded that current evidence is insufficient to assess the balance of benefits and harms of prostate cancer screening. An estimated 218,890 U.S. men were diagnosed with prostate cancer in 2007, and one in six men will be diagnosed in his lifetime.

Screening for prostate cancer is most often performed using PSA tests and digital rectal exams. The PSA test is more likely to detect prostate cancer than the digital rectal exam. However, prostate cancers that are found with a PSA test take years to affect health; most prostate cancers that grow serious enough to cause death take more than 10 years to do so. Since a 75-year-old man has an average life expectancy of about 10 years and is more likely to die from other causes such as heart disease or stroke, prostate cancer screening is unlikely to help men over 75 live longer.

For the same reasons, men younger than 75 with chronic medical problems and a life expectancy of fewer than 10 years are also unlikely to

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Alternative Dosing Method May Help Vaccine Development

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response against prostate-specific antigen. In the study, researchers examined the side effects and immune responses of patients treated with a three-pronged approach: the vaccine, radiation therapy, and an alternative dosing regimen of an immune system booster, interleukin-2. The patients all had localized prostate cancer, had not undergone surgery to remove the prostate, and were candidates for radiation therapy as their primary form of treatment.

“Developing an alternative method of administering vaccine therapy that is well tolerated by most patients and produces similar immune responses to standard methods may help further the development of vaccine therapies for prostate cancer,” said James Gulley, of NCI’s Center for Cancer Research.

Therapeutic cancer vaccines are designed to treat cancer by stimulating the immune system to attack tumor cells without harming normal cells. Several proteins, including PSA, are overexpressed, or produced in excess amounts, by cancer cells and have shown potential to serve as triggers in initiating immune responses. These findings have led to the development of cancer vaccines that target these proteins. The proteins are also known as tumor-associated antigens. To heighten the body’s natural defenses, immune system boosters, such as IL-2, are often given with the vaccines. IL-2 administration, however, is frequently associated with substantial side

effects, including fatigue and high blood sugar.

In a previous study involving the same prostate cancer vaccine, IL-2 was given to 19 patients daily for five days during each 28-day vaccine treatment cycle, and a large majority of the patients had to have the dose of IL-2 reduced or discontinued, primarily because of fatigue.

In this new study, the researchers sought to decrease the side effects associated with IL-2. To do this, the team treated 18 patients with the vaccine and radiation therapy, but with lower doses of IL-2 given over a longer period of time. The patients received the same total amount of IL-2 as in the previous study, but it was administered in smaller daily doses for 14 days of each 28-day treatment cycle.

With metronomic dosing, less than a quarter of the patients had side effects that required their dose of IL-2 to be reduced.

The research team also found that metronomic dosing of IL-2 produced effects on immune cell populations and immune responses that were similar to those observed previously with the standard dosing method. Five of eight evaluated patients had at least a three-fold increase in immune cells that were directed against PSA. The researchers also noted that, similar to the standard dosing method, metronomic dosing of IL-2 induced immune responses against other prostate cancer antigens in some patients.

“Based on safety and feasibility, metronomic dosing appears to be superior to standard dosing and administration,” said Gulley. “More research is needed to evaluate the efficacy of this dosing method in treating prostate cancer.”

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Quality Of Care Varies Widely For Prostate Cancer, Study Says

Quality of care varies greatly for the treatment of men with early-stage prostate cancer by region of the country and category of health care facility, suggesting the potential for improved patient outcomes with more standard treatment protocols, according to a study published in the Aug. 1 issue of the Journal of Clinical Oncology.

The inconsistencies in care also suggest that there is much to do before quality improvement initiatives, such as pay-for-performance, can be instituted nationwide, according to Benjamin Spencer, the lead author of the study and a urologic oncologist at NewYork-Presbyterian Hospital/Columbia University Medical Center and an assistant professor of urology

at the Columbia University College of Physicians and Surgeons.

“We found significant variations for early-stage prostate cancer quality indicators,” Spencer said. “There were differences in care from community hospitals to cancer centers to teaching hospitals. There were also disparities in care from one region of the country to another. But there were no racial disparities, suggesting equity in care once a patient initiates treatment. If these variations in care can be eliminated, thereby providing uniform quality, it may lead to improved outcomes for patients.”

The study reviewed national databases and individual patient charts to identify gaps in care for prostate cancer using comprehensive quality measures developed by RAND.

All therapies for localized prostate cancer can significantly impact the patient’s quality of life. Improving the quality of care throughout the health care system could greatly improve quality-of-life issues for men treated for the disease.

Compliance with structural measures, such as having more than one board-certified urologist and board-certified radiation oncologist on staff, was high at near or greater than 90 percent. In contrast, compliance with standards for pre-therapy assessments of sexual and bowel function was low, at less than 52 percent.

Comprehensive cancer centers and teaching/research hospitals had higher compliance rates than community cancer centers across the board on nearly all compliance measures.

Compliance rates varied greatly throughout the country on several measures, including board-certified urologists and radiation oncologists, communication with primary care physician and conformal total radiation dose.

High-quality care is possible, as evidenced by the near or greater than 80 percent compliance with pre-therapy disease severity assessment and counseling indicators. However, compliance was substantially lower for pre-therapy functional assessment and post-treatment follow-up indicators.

Using the National Cancer Data Base, the study sampled early-stage prostate cancer cases diagnosed in 2000 through 2001 and explicitly reviewed medical records from 2,775 men treated with radical prostatectomy or external-beam radiation therapy. The researchers determined compliance with 29 quality-of-care disease-specific structure and process indicators developed by RAND, stratified by race, geographic region and hospital type.

Prostatectomy Improves Outcome In Some Men

Men with early prostate cancer who undergo radical prostatectomy have a lower rate of death due to prostate cancer than men who are followed without treatment, known as watchful waiting, according to a randomized controlled trial published in the Aug. 12 online issue of the Journal of the National Cancer Institute.

The benefit from the surgery, with respect to prostate cancer death rates, remained constant beyond 10 years, but the overall death rates in the two groups were not statistically different. The applicability of the results to the current generation of prostate cancer patients is unclear, however, because few of the cancers treated in the trial were discovered by PSA (prostate-specific antigen) screening, a practice that is now widespread.

The Scandinavian Prostate Cancer Group launched the current trial in 1989 to examine the impact of radical prostatectomy on cancer-specific mortality relative to watchful waiting.

In 2005, with a median follow-up 8.2 years, the researchers reported that men in the prostatectomy arm had lower rates of disease-specific mortality than those in the watchful waiting arm. The investigators were interested to know if the prostate cancer mortality difference would continue to increase with longer follow-up. Thus far, this is the only completed randomized trial comparing the two treatment options.

Lars Holmberg, of the Kings College Medical School in London and colleagues from Finland and Sweden continued to follow the men for an additional three years.

With a median follow-up of 10.8 years, the cumulative incidence rate for prostate cancer death was 13.5 percent in the surgery arm and 19.5 percent in the watchful waiting arm, for an absolute reduction of 6 percent. The benefit, in terms of absolute risk reduction, did not increase after the first 10 years following treatment. For those patients followed at least 12 years, 12.5 percent of the men in the surgery group died due to prostate cancer compared with 17.9 percent of the men in the watchful waiting group, for an absolute reduction of 5.4 percent. Overall mortality at 12 years, however, was not statistically significantly different in the two arms at 32.7 percent and 38.5 percent, respectively.

“Contrary to our predictions based on shorter follow-up, the absolute difference in cumulative incidence of distant metastasis and prostate cancer death did not further increase after 7–9 years of follow-up,”

the authors write.

The authors note that it is not clear whether their data are applicable to men whose cancer is detected in the era of PSA screening because most of the men in their trial had palpable tumors at diagnosis. “In settings with a large proportion of PSA-detected tumors, the relative reduction in risk of death following radical prostatectomy might be somewhat larger or similar to that in our study, but the absolute reduction would be smaller,” they write.

In an accompanying editorial, Timothy Wilt, of the Minneapolis VA Center for Chronic Disease Outcomes Research also raises that issue but concludes that the results are applicable to a subset of current prostate cancer patients. “These results demonstrate that among men younger than 65 years whose prostate cancer is detected by methods other than PSA testing (eg, due to a digital rectal examination to evaluate urinary or other symptoms), cure with radical prostatectomy is possible, may be necessary, and should generally be recommended,” he writes.

He notes that the trial is only the first in a series that are evaluating treatments for men with localized prostate cancer, and that at least one included patients whose tumors were discovered through PSA testing. These trials and trials testing options between these two extremes will be important in guiding prostate cancer care in the future.

Cancer Screening: **Prostate Cancer Detection May Not Benefit Older Men**

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benefit from screening. There are also harms associated with prostate cancer screening, which include biopsies, unnecessary treatment and false-positive results that may lead to anxiety. Complications often result from treating prostate cancer and may include urinary incontinence and impotence. These slow-growing cancers may never have affected a patient’s health or well-being had they not been detected by screening.

“Because many prostate cancers grow slowly, early detection may not benefit a patient’s health and in some cases may even cause harm,” said Task Force Chair Ned Calonge, who is also chief medical officer for the Colorado Department of Public Health and Environment. “We encourage men younger than 75 to discuss with their clinicians the potential—but uncertain—benefits and the possible harms of getting the PSA test before they decide to be screened.”

Current data show that one-third of all men in the U.S. over 75 are receiving PSA testing. Although most major medical organizations suggest that prostate cancer screening may be discontinued in men with a life expectancy of fewer than 10 years, the Task Force is the first group to define an explicit age cutoff above which screening is likely to be ineffective or harmful.

The results of two ongoing clinical trials—the National Cancer Institute’s Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial and the European Study of Screening for Prostate Cancer—should help to clarify the potential benefits of screening in men under the age of 75.

The Task Force is the leading independent panel of experts in prevention and primary care. The Task Force, which is supported by AHRQ, conducts rigorous, impartial assessments of the scientific evidence for the effectiveness of a broad range of clinical preventive services, including screening, counseling, and preventive medications. Its recommendations are considered the gold standard for clinical preventive services.

The recommendations and materials for clinicians are available on the AHRQ Web site at <http://www.ahrq.gov/clinic/uspstf/uspSprca.htm>.

For men who have been diagnosed with prostate cancer, AHRQ has two new plain-language guides that compare the effectiveness and risks of prostate cancer treatments. More information about the guides is available at <http://www.effectivehealthcare.ahrq.gov>.

Breast Cancer: **Risk of Relapse Continues After Five Years of Therapy**

Breast cancer survivors continue to have a substantial risk of disease recurrence after five years of systemic therapy, according to a study published in the August 12 online issue of the Journal of the National Cancer Institute.

Among breast cancer patients who were cancer-free five years after initiating systemic therapy, 89 percent remained recurrence-free at five years (approximately 10 years after a woman’s initial diagnosis) and 80 percent remained recurrence free at 10 years (approximately 15 years after diagnosis).

Women who receive chemotherapy, hormone therapy, or both, in addition to surgery, have a higher rate of relapse-free survival than women who do not receive adjuvant or neoadjuvant therapy. However, even following systemic therapy, breast cancer

survivors remain at risk for relapse. Few studies have evaluated the magnitude of that risk or the patient and tumor characteristics that are associated with disease recurrence.

In the study, Abenaa Brewster, of the University of Texas M. D. Anderson Cancer Center in Houston and colleagues examined the recurrence rate in 2,838 breast cancer patients who had been treated between 1985 and 2001 at the cancer center and were included in the center's tumor registry.

To determine the magnitude of residual risk following adjuvant therapy, which might include five years of hormone therapy, the researchers looked at what happened to the women five years after the start of treatment.

After a median follow-up period of 28 months, 216 women developed recurrent disease. The five-year risk of relapse for women with stage I disease was 7 percent, 11 percent for women with stage II disease, and 13 percent for women with stage III disease. Tumor grade, hormone receptor status, and endocrine therapy were all statistically significantly associated with risk of recurrence.

The increased risk of disease recurrence after five years of therapy for women with hormone receptor positive cancer points to an area of unmet clinical need. While there are risk-reduction options for postmenopausal women who have completed five years of tamoxifen therapy, none exist for premenopausal women. New strategies need to be developed for these women to further reduce their risk.

"In conclusion, this study demonstrates that patients with early stage breast cancer who are disease free at five years after [adjuvant systemic therapy] have a substantially increased residual risk of recurrence," the authors write.

Two Breast Cancer Screening Methods Found Equivalent

An organized population-based breast cancer screening program in Norway and an approach to screening that relies on physician- and self-referrals in Vermont are equally sensitive for detecting cancer, researchers report in the July 29 online issue of the *Journal of the National Cancer Institute*. But the recall rate for abnormal mammograms was lower in Norway.

Breast cancer screening in the U.S. is usually initiated in response to a physician's recommendation

(known as "opportunistic screening"), and women are advised to have annual screening mammograms. By contrast, breast cancer screening programs in Norway and in some other European countries regularly send letters to all women in a specific age range inviting them to have a screening mammogram. The Norway program aims for women to be screened every two years. The differences between the two approaches make it relatively difficult to compare their effectiveness, and few studies have aimed to do so previously.

In the study, Berta Geller, of the University of Vermont in Burlington, Solveig Hofvind, of the Cancer Registry of Norway, and colleagues compared the screening approaches by looking at the percentage of women who were recalled for a re-evaluation, the screening detection rate of breast cancer, and the rate of interval cancers in 45,050 women in Vermont and 194,430 women in Norway from 1997 to 2003. Women included in the study were aged 50 to 69 years at the time of screening.

The age-adjusted screening detection rate of cancers was similar between the two populations (2.77 per 1,000 woman-years in Vermont versus 2.57 in Norway), however, more than three times as many women were recalled in Vermont than in Norway (9.8 percent versus 2.7 percent, respectively).

The rate of interval cancers was higher in Vermont than in Norway (1.24 per 1,000 woman-years versus 0.86), and 55.9 percent of the interval cancers were 15 mm or smaller in Vermont compared with 38.2 percent of the interval cancers in Norway.

When all cancers detected during regular screening and between screening mammograms were combined, there were no substantial differences in the prognostic features of invasive cancers detected in the two populations.

The researchers conclude that although most of the women in Vermont were screened twice as often as the women in Norway, the overall rate of cancer detection was similar.

Given the shorter interval between screens, Geller and colleagues were surprised to find a higher interval cancer rate in the Vermont women and hypothesize that "Vermont women and/or their health care providers may more readily pursue evaluation of symptoms and clinical findings than their Norwegian counterparts."

"Our results demonstrate that despite its longer screening interval, the organized population-based screening program in Norway achieved similar outcomes as the opportunistic screening in Vermont," the authors write.

Zometa Prevents Bone Loss In Premenopausal Women

A multicenter, Phase III study conducted by researchers at Columbia University Medical Center showed that the osteoporosis drug zoledronic acid (Zometa) prevents bone loss at 12 months in premenopausal women undergoing chemotherapy following surgery for early-stage breast cancer.

The study, published online Aug. 18 in the *Journal of Clinical Oncology* is the first study to evaluate the use of the drug in premenopausal breast cancer patients, but previous studies have shown that similar drugs prevent bone loss during and following chemotherapy in this group.

Zoledronic acid has been shown to prevent bone loss in postmenopausal women, and recent findings have indicated that it reduces risk of recurrence in women with breast cancer.

“Our study confirms that women experience significant bone loss due to cancer treatments and that zoledronic acid can prevent this loss,” said Dawn Hershman, assistant professor of medicine at Columbia University’s College of Physicians and Surgeons and the study’s lead author. “While our findings are promising, it’s too early for us to recommend this drug for all premenopausal women undergoing chemotherapy for breast cancer because we don’t yet have all the information we need on dosing, cost effectiveness, and whether this drug actually prevents bone fractures. However, this research does show we need to be more vigilant about monitoring patients’ bone densities before and during treatment so we can protect bone health and offset bone fracture or osteoporosis risk.”

The randomized, double-blind, multicenter phase III trial compared treatment with zoledronic acid or placebo every three months for one year; 101 patients were enrolled in the trial and 85 completed it.

All patients in the trial were given oral vitamin D and calcium supplements. Primary measure of bone loss was change in bone mineral density, measured via scans of the lower spine and hip. Scans were performed prior to chemotherapy and at six and 12 months.

Patients who received zoledronic acid had stable BMDs at both six and 12 months. Patients who received placebo showed a significant decline in spine BMD: 2.4 percent at six months and 4.1 percent at 12 months. In the hip, BMD declines were 0.8 percent at six months and 2.6 percent at 12 months.

Side effects did not differ significantly between the two groups.

Risk Assessment Key In Long-Term Treatment

Breast cancer patients and their physicians may make more informed, long-term treatment decisions using risk assessment strategies to help determine probability of recurrence, a research team led by scientists at the University of Texas M. D. Anderson Cancer Center reported in the Aug. 12 online issue of the *Journal of the National Cancer Institute*.

The 2,838 women studied were diagnosed with stage I through III breast cancers and had been treated with adjuvant systemic therapy (AST), such as chemotherapy and or tamoxifen between 1985 and 2001, and were in the M. D. Anderson Tumor Registry. The patients in the study were five years from the start of their AST and were cancer-free. The researchers calculated the residual or remaining risk of recurrence from the benchmark of five years from the start of AST and determined the factors that contributed to a higher residual risk of recurrence.

“Understandably, one of the most common questions posed by breast cancer survivors is ‘What are the chances of it coming back?’” said the study’s lead author, Abenaa Brewster, assistant professor in M. D. Anderson’s Department of Clinical Cancer Prevention. “Now we can tell some women within a certain percentage their future risk of recurrence and clinicians may be able to make more informed decisions regarding prescription of extended adjuvant endocrine therapy.”

Data analysis revealed that 89 percent of the study populations did not experience a recurrence at five years (approximately 10 years after a woman’s initial diagnosis), and 80 percent did not experience a recurrence at 10 years (approximately 15 years after diagnosis).

Brewster commented that, while reassuring for most of the five-year survivors, the percentage of the population who had a recurrence is significant to oncologists.

“The magnitude of risk of recurrence should indicate a need for us to consider extended endocrine treatment for eligible women to further lower their risks,” said Brewster. Also, the study did not include women who received adjuvant systemic therapy with trastuzumab or five years of aromatase inhibitor treatment and therefore the residual risk of recurrence among those groups of patients could not be determined.

Median follow-up time for women in the study was 28 months. During that time, 216 of the women

experienced a recurrence. The five-year residual risks of recurrence for patients with stage I, II and III cancers were 7 percent, 11 percent and 13 percent respectively. Patients with stage II or III versus stage I disease and patients with grade I versus grade III tumors had a higher risk of late recurrence. Patients who had estrogen receptor-positive tumors who received adjuvant endocrine therapy also had a higher risk of recurrence than those with hormone receptor-negative tumors but the difference was not found to meet statistical significance.

The study also indicated a need for the continued development of risk-reduction strategies for premenopausal breast cancer survivors because of lack of available therapies in this younger age group. Currently, extended adjuvant endocrine therapy with letrozole (Femara) is available only for post-menopausal patients with hormone receptor positive tumors who have completed five years of tamoxifen therapy.

Cancer Education: **Survey Finds Misconceptions About Cancer Worldwide**

Many people hold mistaken beliefs about what causes cancer, tending to inflate the threat from environmental factors that have relatively little impact while minimizing the hazards of behaviors well established as cancer risk factors, according to the first global survey on the topic.

The survey, conducted by Roy Morgan Research and Gallup International on behalf of the International Union of Against Cancer (UICC), identified key areas where misconceptions could be addressed and where lives could be saved.

The survey involved interviewing 29,925 people in 29 countries across the globe during the last year. It is the first study to provide internationally comparable data on perceptions about cancer risk factors. The results, which allow for comparison between high-, middle- and low-income countries, were released Aug. 27 at the UICC's World Cancer Congress in Geneva.

Key findings from the survey include:

—People in high-income countries were the least likely to believe that drinking alcohol increases the risk of cancer. In that group, 42% said alcohol does not increase the risk. That compares with only 26% of respondents in middle-income countries and 15% in low-income countries saying that alcohol use does not increase the risk of cancer. In fact, cancer risk rises as alcohol intake increases.

—In high-income countries, the hazards of not eating enough fruits and vegetables scored more highly as a perceived risk (59%) than alcohol intake did (51%), even though the scientific evidence for the protective effect of fruit and vegetables is weaker than the evidence that alcohol intake is harmful.

—In rich countries, stress (57%) and air pollution (78%) scored higher as perceived risk factors for cancer than did alcohol intake. However, stress is not recognized as a cause of cancer and air pollution is a minor contributor compared with alcohol consumption.

—People in low- and middle-income countries have more pessimistic beliefs about cancer treatment than those in high-income countries. One of the more important problematic beliefs in lower-income countries concerned perceptions about the curability of cancer. The survey found that in such countries 48% said that “not much can be done” to cure cancer or that they didn't know whether anything could be done. That compares with 39% in middle-income countries and 17% in high-income countries. These misconceptions might deter people from participating in cancer screening programs.

—In general, people in all countries are more ready to accept that things outside of their control might cause cancer (such as air pollution), than things that are within their own control (such as overweight, which is a well-established cancer risk factor).

—In low-income countries, 75% percent said their preference was for their doctor to make all the treatment decisions. Only 8% said the doctor and patient should decide together and 9% said the patient should decide. That compares with a preference in rich countries for a more equitable decision-making style that emphasizes self-determination, with 72% saying either that the decision should be made together or rest with the patient alone.

David Hill, president-elect of UICC and director of the Cancer Council Victoria in Melbourne, Australia, whose team analyzed the survey data, said governments will now have data to put in place education campaigns to address these beliefs and change them.

“The survey reveals there are some big unheard messages,” Hill said. “These kind of data help us to quantify the differences between countries and to highlight where additional efforts are needed. Some of these countries have rarely had any population survey data to help their program planning efforts.”

“We know that people need to be given a reason why they should change,” Hill said. “They need to be shown how to change; they need to be given resources

or support to change; they need to remember to change and they need positive reinforcement for changing. Many of these principles can be applied in designing education programs to encourage and support behavior change.” Hill said the UICC would use the data to push a worldwide agenda to ensure people had more accurate knowledge of cancer as a basis for making cancer control program as effective as they can be.

High-income countries included in the survey: Australia, Austria, , Canada, Czech Republic, Greece, Israel, New Zealand, Spain, UK, U.S. Middle-income countries: Bolivia, China, Dominican Republic, Georgia, Guatemala, Indonesia, Lebanon, Mexico, Panama, Peru, Philippines, Romania, Serbia, Turkey, Ukraine, Venezuela, Uruguay. Low-income countries: Kenya, Nigeria.

NCI Cooperative Group, Cancer Center Trials Listed

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

Phase I

Phase I Trial of the Raf Kinase and Receptor Tyrosine Kinase Inhibitor Sorafenib in Children and Young Adults with Neurofibromatosis Type 1 and Inoperable Plexiform Neurofibromas. NCI Pediatric Oncology Branch, protocol 7856, Widemann, Brigitte, phone 301-496-7387.

Phase I Trial of Concurrent Chemoradiation/Chemoreirradiation with Cetuximab, Sunitinib, and Accelerated Radiation in Patients with Locally Advanced/High-Risk/Recurrent Poor Prognosis Head and Neck Cancer. University of Chicago, protocol 8079, Villafior, Victoria, phone 773-702-2825.

Phase II

Phase II Study of Single Agent Intravenous VEGF Trap in Patients with Poor Prognostic Recurrent and/or Metastatic Thyroid Cancer after RAI Therapy. Memorial Sloan Kettering Cancer Center, protocol 7508, Pfister, David, phone 212-639-8235.

Phase II Trial Exploring the Success of Cryoablation Therapy in the Treatment of Invasive Breast Carcinoma. American College of Surgeons Oncology Trials Group, protocol ACOSOG-Z1072, Simmons, Rache, 212-821-0870.

Phase II Evaluation of Combination Bevacizumab

and Temsirolimus in the Treatment of Recurrent or Persistent Endometrial Carcinoma. Gynecologic Oncology Group, protocol GOG-0229G, Alvarez, Edwin, phone 858-822-6275.

Phase III

Phase III Prospective Randomized Trial Comparing Laparoscopic-Assisted Resection Versus Open Resection for Rectal Cancer. American College of Surgeons Oncology Trials Group, protocol ACOSOG-Z6051, Fleshman, James, phone 314-454-7183.

Other

Identifying the Genetic Basis of Adult AMKL. Eastern Cooperative Oncology Group, protocol E1900T3, Crispino, John, phone 312-503-1504.

Prediction of Overall Survival Using Mass Spectrometry Profiling in Head and Neck Cancer Patients Treated with Epidermal Growth Factor Receptor Inhibitors. Eastern Cooperative Oncology Group, protocol E3301T1, Chung, Christine, phone 615-322-4967.

Screening of Cathepsin G Levels in Multiple Myeloma Patients Receiving Evaluation of Polymorphisms, Mutations Treatment with Thalidomide/Lenalidomide within the ECOG Trials EA100 and E4A03. Eastern Cooperative Oncology Group, protocol E4A03T2, Lentzsch, Suzanne, phone 412-648-6578.

Evaluation of Polymorphisms, Mutations, and Protein Expression by Automated Quantitative Immunohistochemistry in the Lapatinib Targets and Metabolic Pathway in Samples from E5803. Eastern Cooperative Oncology Group, protocol E5803T1, Kolesar, Jill, phone 608-262-5549.

Morphometric Diagnosis of Atypical Glandular Lesions Using a Conventional Pap Smear From GOG-0171 Patients (Enrolled by GOG-Japan) with a Cytologic Diagnosis of Atypical Glandular Cells of Unspecified Significance. Gynecologic Oncology Group, protocol GOG-8007, Kaku, Tsunehisa, phone 81-92-642-67.

Investigation of Thioredoxin-1 Family Protein Expression in Rectal Cancer. Southwest Oncology Group, protocol SWOG-9304A-ICSC, Dragovich, Tomislav, phone 520-626-7725.

Pilot

Quantitative Assessment of the Early and Late Effects of Radiation and Chemotherapy on Glioblastoma Using Multiple MRI Techniques. Massachusetts General Hospital, protocol 8201, Sorensen, Alma Gregory, phone 617-726-3914.